

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
AT CHARLESTON

\_\_\_\_\_ X  
THE CITY OF HUNTINGTON, : Civil Action  
Plaintiff, : No. 3:17-cv-01362  
v. :  
AMERISOURCEBERGEN DRUG :  
CORPORATION, et al., :  
Defendants. :  
\_\_\_\_\_ X  
CABELL COUNTY COMMISSION, : Civil Action  
Plaintiff, : No. 3:17-cv-01665  
v. :  
AMERISOURCEBERGEN DRUG :  
CORPORATION, et al., :  
Defendants. :  
\_\_\_\_\_ X

BENCH TRIAL - VOLUME 23  
BEFORE THE HONORABLE DAVID A. FABER, SENIOR STATUS JUDGE  
UNITED STATES DISTRICT COURT  
IN CHARLESTON, WEST VIRGINIA

JUNE 9, 2021

**APPEARANCES:**

**For the Plaintiff,**  
**Cabell County Commission:**

**MR. PAUL T. FARRELL, JR.**

Farrell & Fuller, LLC  
1311 Ponce De Leon, Suite 202  
San Juan, PR 00907

**MR. ANTHONY J. MAJESTRO**

Powell & Majestro  
Suite P-1200  
405 Capitol Street  
Charleston, WV 25301

**MR. DAVID I. ACKERMAN**

Motley Rice  
Suite 1001  
401 9th Street NW  
Washington, DC

**MR. PETER J. MOUGEY**

Levin Papantonio Thomas Mitchell Rafferty & Proctor  
Suite 600  
316 South Baylen Street  
Pensacola, FL 32502

**MR. MICHAEL J. FULLER, JR.**

Farrell & Fuller  
Suite 202  
1311 Ponce De Leon  
San Juan, PR 00907

**APPEARANCES (Continued) :**

**For the Plaintiff,**  
**Cabell County Commission:**

**MS. MILDRED CONROY**

The Lanier Law Firm  
Tower 56  
126 East 56th Street, 6th Floor  
New York, NY 1022

**MS. PEARL A. ROBERTSON**

Irpino Avin Hawkins Law Firm  
2216 Magazine Street  
New Orleans, LA 70130

**MR. MICHAEL W. WOELFEL**

Woelfel & Woelfel  
801 Eighth Street  
Huntington, WV 25701

**MR. CHARLES R. WEBB**

The Webb Law Center  
716 Lee Street East  
Charleston, WV 25301

**MS. ANNIE KOUBA**

Motley Rice  
28 Bridgeside Blvd.  
Mt. Pleasant, SC 29464

**MR. MARK P. PIFKO**

Baron & Budd  
Suite 1600  
15910 Ventura Boulevard  
Encino, CA 91436

**For the Plaintiff,  
City of Huntington:**

**MS. ANNE MCGINNESS KEARSE**  
Motley Rice  
28 Bridgeside Blvd.  
Mt. Pleasant, SC 29464

**MS. LINDA J. SINGER**  
Motley Rice  
Suite 1001  
401 Ninth Street NW  
Washington, DC 20004

**MS. TEMITOPE LEYIMU**  
Motley Rice  
28 Bridgeside Blvd.  
Mt. Pleasant, SC 29464

**For the Defendant,  
Cardinal Health:**

**MS. ENU MAINIGI**  
**MS. JENNIFER WICHT**  
Williams Connolly  
725 Twelfth Street NW  
Washington, DC 20005

**MS. SUZANNE SALGADO**  
725 Twelfth Street NW  
Washington, DC 20005

**MR. STEVEN R. RUBY**  
Carey Douglas Kessler & Ruby  
901 Chase Tower  
707 Virginia Street, East  
Charleston, WV 25301

**APPEARANCES (Continued) :**

**For the Defendant,**  
**Cardinal Health:**

**MS. ASHLEY W. HARDIN**  
**MS. ISIA JASIEWICZ**  
Williams & Connolly  
25 Twelfth Street, NW  
Washington, DC 20005

**APPEARANCES (Continued) :**

**For the Defendant,**  
**McKesson:**

**MR. TIMOTHY C. HESTER**  
**MR. PAUL W. SCHMIDT**  
**MS. LAURA M. FLAHIVE WU**  
**MR. ANDREW STANNER**  
Covington & Burling  
One City Center  
850 Tenth Street NW  
Washington, DC 20001

**MR. JEFFREY M. WAKEFIELD**  
Flaherty Sensabaugh & Bonasso  
P.O. Box 3843  
Charleston, WV 25338-3843

**APPEARANCES (Continued) :**

**For the Defendant,**  
**AmerisourceBergen Drug Corporation:**

**MS. SHANNON E. MCCLURE**

**MR. JOSEPH J. MAHADY**

Reed Smith  
Three Logan Square  
Suite 3100  
1717 Arch Street  
Philadelphia, PA 19103

**MS. GRETCHEN M. CALLAS**

Jackson Kelly  
P.O. Box 553  
Charleston, WV 25322

**APPEARANCES (Continued) :**

**MR. ROBERT A. NICHOLAS**

Reed Smith  
Suite 3100  
Three Logan Square  
1717 Arch Street  
Philadelphia, PA 19103

**MS. ELIZABETH CAMPBELL**

1300 Morris Drive  
Chesterbrook, PA 19087

Court Reporter:

Ayme Cochran, RMR, CRR

Court Reporter:

Lisa A. Cook, RPR-RMR-CRR-FCRR

Proceedings recorded by mechanical stenography;  
transcript produced by computer.

1                   PROCEEDINGS had before The Honorable David A.  
2                   Faber, Senior Status Judge, United States District  
3                   Court, Southern District of West Virginia, in  
4                   Charleston, West Virginia, on June 9, 2021, at 9:00  
5                   a.m., as follows:

6                   THE COURT: Mr. Fuller, you have something you  
7                   want to bring up?

8                   MR. FULLER: Judge, just real briefly. We had  
9                   previously admitted P-14288 that didn't have page numbers on  
10                  it and it is a voluminous document, so we're going to  
11                  substitute in, with the Court's permission, a paginated  
12                  version.

13                  And then P-14290, these are Cardinal's policies and  
14                  procedures. Cardinal has no objection and the clerk said it  
15                  was okay to give it to her on a thumb drive because it's  
16                  voluminous, if that's all right with the Court.

17                  THE COURT: Okay. You may do so, Mr. Fuller.

18                  MR. FULLER: Thank you, Judge.

19                  THE COURT: I have what I think will be welcome  
20                  news. In consultation with the Chief Judge and the Clerk of  
21                  Court, I'm authorized to tell you that fully vaccinated  
22                  individuals can go without masks while in the courtroom.

23                  (Applause)

24                  THE COURT: In this courtroom. And you still have  
25                  to comply with the mask order while in common areas and

1 maintain the occupational limits that were put in place at  
2 the beginning of the trial and these rules are being  
3 constantly re-evaluated, I'm told, but at least while you're  
4 in this courtroom, you don't have to wear the masks.

5 SIMULTANEOUS SPEAKERS: Thank you, Your Honor.

6 THE COURT: So, I'm no longer setting a bad  
7 example.

8 (Laughter)

9 THE COURT: Also, I'm struggling about the time  
10 limitations on the court and I am trying to work through a  
11 proposal for you on that, but for now, unless somebody has  
12 travel plans that are going to be totally disrupted by this,  
13 we will go until 5:00 on Friday. Is that a problem with  
14 anybody? I see no -- okay.

15 And I'm trying to figure out a way to maybe allow a  
16 little more time without disrupting the trial schedule, but  
17 I'll try to have a proposal to you for that shortly.

18 Are we ready to go with Mr. Rannazzisi?

19 Are you in the courtroom, sir?

20 MR. SCHMIDT: May I take the podium, Your Honor?

21 THE COURT: Yes.

22 MR. SCHMIDT: Thank you.

23 THE COURT: And, Mr. Rannazzisi, you don't have to  
24 wear the mask anymore in this courtroom, but you have to  
25 follow all the other rules that are in place.

1                   THE WITNESS: Thank you very much, Judge. That's  
2 great.

3                   THE COURT: The abominable masks.

4                   THE WITNESS: And good morning, Your Honor.

5                   THE COURT: Good morning, sir.

6 You may proceed, Mr. Schmidt.

7                   MR. SCHMIDT: Thank you, Your Honor.

8                   Good morning, Mr. Rannazzisi.

9                   THE WITNESS: Good morning.

10                  MR. SCHMIDT: Good morning again, Your Honor.

11                  May I approach?

12                  BY MR. SCHMIDT:

13                  **Q.** Mr. Rannazzisi, I'd like to turn next to some of your  
14 testimony from the past two days about the suspicious order  
15 reporting process and I want to start with what I've passed  
16 you as DEF-WV-640. Do you recognize this as including the  
17 suspicious order regulation from the DEA website?

18                  **A.** Yes.

19                  MR. SCHMIDT: I don't think we've previously moved  
20 this into evidence. I'll go ahead and do that. DEF-WV-640.

21                  THE COURT: Any objection?

22                  MR. ACKERMAN: No objection.

23                  THE COURT: It's admitted.

24                  BY MR. SCHMIDT:

25                  **Q.** So, what I'd like to do, Mr. Rannazzisi, is could we

1       cull out Subsection (b), as in boy? Do you recognize this  
2       as the relevant suspicious order regulation?

3       **A.** Yes.

4       **Q.** And it says the registrant shall design and operate a  
5       system to disclose to the registrant suspicious orders of  
6       controlled substances. The registrant shall inform the  
7       Field Division Office of the administration in his area of  
8       suspicious orders when discovered by the registrant. And  
9       then here's the language I want to focus on. Suspicious  
10      orders include orders of, and can we underline unusual size  
11      or highlight it, and then orders, quote, "deviating  
12      substantially from a normal pattern", and, quote -- and  
13      orders of, quote, "unusual frequency". Do you see that?

14       **A.** Yes.

15       **Q.** And these three criteria that we've highlighted are the  
16      only criteria specified in this regulation, unusual size,  
17      deviating substantially from a normal pattern, unusual  
18      frequency, correct?

19       **A.** That is correct, yes.

20       **Q.** You talked over the past couple days about something  
21      you refer to as truly suspicious. Is -- when you were  
22      talking about something that is truly suspicious, is that  
23      something different than a company making a judgment in  
24      their view that an order is of unusual size, deviating  
25      substantially from a normal pattern, or unusual frequency?

1       Is there any difference between those two, just yes or no,  
2       if you can?

3       **A.**     No. There's no difference.

4       **Q.**     In fact -- and there's no greater -- let me try it this  
5       way. When you were at DEA you told companies that in terms  
6       of interpreting what this language means, in terms of  
7       applying it, DEA cannot tell a distributor if an order is  
8       suspicious under these criteria, correct?

9       **A.**     It was up to the distributor to make the decision  
10      whether an order is suspicious or not, yes.

11      **Q.**     And you told them DEA cannot tell a distributor if an  
12      order is suspicious, true?

13      **A.**     Yes, that's true.

14      **Q.**     It was up to them?

15      **A.**     Yes.

16      **Q.**     And in terms of DEA itself, DEA had no internal  
17      guidance for what is a suspicious order, correct?

18      **A.**     There was no guidance except for the regulation, yes.

19      **Q.**     On your watch as Head of Diversion Control from 2005 to  
20      2015, DEA never had internal guidance as to what constituted  
21      a Suspicious Order Monitoring System that complied with  
22      regulations, correct?

23      **A.**     Yes, that is correct.

24      **Q.**     Are you aware that DEA has proposed to amend this  
25      regulation?

1       **A.**     I believe that -- I don't know what DEA is doing, but I  
2 believe that Congress actually codified that regulation.

3       **Q.**     Do you know if DEA has proposed a rule making process  
4 to amend this regulation?

5       **A.**     I don't know.

6       **Q.**     Okay. You talked about having responsibility for  
7 promulgating regulations, correct?

8       **A.**     That's correct.

9       **Q.**     You never amended this regulation on your watch, did  
10 you?

11      **A.**     No, I did not.

12      **Q.**     Did you ever try internally to add language to this  
13 regulation that would go to any of the points you've talked  
14 about in your testimony, do not ship, explain why an order  
15 is being reported, only report truly suspicious? Did you  
16 ever attempt internally to amend the regulation on any of  
17 those grounds?

18      **A.**     No, I did not.

19      **Q.**     Now, I want to come to an idea I just touched on, which  
20 is do you remember talking about explaining -- distributors  
21 explaining why suspicious orders were being reported? Do  
22 you remember giving --

23      **A.**     Can you repeat that one more time?

24      **Q.**     Sure. You gave testimony on several times that you  
25 weren't getting explanations for why suspicious orders were

1 being reported. Do you remember saying that?

2 **A.** Yes.

3 **Q.** And I'll come back to what the distributors actually  
4 did explain, but before I do that, I want to go to this  
5 regulation as left unamended by you. There's no language in  
6 this regulation saying explain why you consider it to be of  
7 unusual size, deviating substantially from a normal pattern,  
8 or of unusual frequency, correct?

9 **A.** That is correct.

10 **Q.** And you never sought to amend the regulation to require  
11 such an explanation, correct?

12 **A.** We did not amend the regulation, that's correct.

13 **Q.** All right. I want to follow up on testimony you had  
14 about there not being any policy change at DEA when you came  
15 into place and I want to focus on this 2005 to 2008 window,  
16 if that's okay.

17 **A.** Okay. Yes, sir.

18 **Q.** And do you have the understanding that, as the Court  
19 has heard through testimony, by 2008 every defendant in this  
20 case had a policy in place that involved blocking flagged  
21 orders? Do you have that understanding?

22 **A.** From my knowledge at DEA?

23 **Q.** Yes, sir.

24 **A.** Yes.

25 **Q.** Okay. And you agree that if an order is blocked the

1                   medicine cannot be diverted?

2                   **A.**     If the order is blocked, the medicine can't go  
3                   downstream.

4                   **Q.**     And it can't be diverted, correct?

5                   **A.**     That's correct.

6                   **Q.**     And from your time at DEA you can't identify any orders  
7                   in Huntington or Cabell County that you believed that DEA  
8                   should have been blocked by one of the defendants but were  
9                   not, correct?

10                  MR. ACKERMAN: Objection, Your Honor, and this  
11                  goes to the scope of Mr. Rannazzisi's deposition. The words  
12                  "West Virginia" don't appear in the deposition transcript,  
13                  so --

14                  THE COURT: Overruled. This is cross examination.  
15                  I'll allow it. Go ahead.

16                  THE WITNESS: No, I have not reviewed any  
17                  documents related to West Virginia.

18                  BY MR. SCHMIDT:

19                  **Q.**     So, let me focus still on this time period when you  
20                  came in from 2005 through 2008 and even into 2009. Am I  
21                  correct that before 2006 and 2007 you have no firsthand  
22                  knowledge about whether the DEA was aware that it had  
23                  earlier been standard practice in the industry to file  
24                  Suspicious Order Reports while continuing to ship product?  
25                  Am I correct you have no firsthand knowledge on that point?

1       **A.**     Could you -- what do you feel is firsthand knowledge?

2       **Q.**     Whatever you consider firsthand knowledge. And if it  
3     helps to show you your testimony, I can show you your  
4     testimony.

5       **A.**     I have no -- I have no direct knowledge except for what  
6     my staff told me.

7       **Q.**     And I'm not going to ask you about discussions because  
8     of hearsay. You've talked about effective controls against  
9     diversion; you remember that, right?

10      **A.**     Yes.

11      **Q.**     Am I correct that prior to the Fall of 2005 and since  
12     1970, you can't recall any type of document or guidance  
13     where the distributors were told to do certain things that  
14     were related to maintaining effective controls against  
15     diversion?

16      **A.**     That's correct.

17      **Q.**     And am I correct you've not watched the testimony in  
18     this case to see testimony from individual witnesses at  
19     individual companies where they said prior to 2008 if they  
20     saw something that they thought was likely to be diverted  
21     they would block it? Have you seen that testimony?

22      **A.**     I have not seen that testimony, no.

23      **Q.**     Do you know what the practice was prior to 2005 with  
24     the defendants in this case when they saw an order that was  
25     likely to be diverted?

1       **A.**     I only know what I was briefed on at the time, yes.

2       **Q.**     For example, did you review McKesson's Section 55 of  
3           this Drug Operation Manual to see that practice of blocking  
4           orders that were actually likely to be diverted before 2008  
5           codified in the manual? Have you reviewed the manual to see  
6           that?

7       **A.**     When I was with DEA?

8       **Q.**     Yes, sir.

9       **A.**     No, I didn't review the manual but, again, I was  
10          briefed on that before the Orders to Show Cause were issued.

11       **Q.**     Do you remember being briefed on that provision of the  
12          manual?

13       **A.**     I was briefed on the overall -- the overall system  
14          before the -- before the Order to Show Cause was issued. I  
15          was briefed on the overall system.

16       **Q.**     That included a portion of McKesson's manual that  
17          codified the practice of blocking orders that actually  
18          appeared like they were likely to be diverted before 2008?

19       **A.**     I don't recall the specific provisions that I was  
20          briefed on.

21       **Q.**     Let's look at your 2006 letter, please. Do you  
22          recognize this as your September 27, 2006 letter?

23       **A.**     Yes.

24       **Q.**     And if we go to Page 2, I want to pick up on a sentence  
25          you were asked about.

1       **A.**    Okay.

2       **Q.**    In the second paragraph, the first sentence, DEA  
3           recognizes that the overwhelming majority of registered  
4           distributors act lawfully and take appropriate measures to  
5           prevent diversion. Did you believe that statement to be  
6           true when you said it in September of 2006?

7       **A.**    Yes.

8       **Q.**    You don't know of any distributor that was blocking  
9           suspicious orders instead of shipping them and reporting  
10          before 2008, correct?

11      **A.**    Could you repeat that one more time?

12      **Q.**    Of course I can. You don't know of any distributor  
13          that was blocking suspicious orders instead of shipping them  
14          and reporting them before 2008, correct?

15      **A.**    Blocking suspicious orders before shipping and  
16          reporting them? Well, if they were blocking them, they  
17          wouldn't be shipping them. So, no, I don't know of anybody.

18      **Q.**    In place of? Do you know of any distributor that was  
19          blocking suspicious orders instead of shipping and reporting  
20          them before 2008?

21      **A.**    I don't believe -- no, I don't, because they were  
22          continuing to ship downstream.

23      **Q.**    Okay. And you don't know whether it's true or false  
24          that no distributor blocked suspicious orders before sending  
25          them prior to 2006 when you wrote this letter that you

1 recognize that the overwhelming majority of registered  
2 distributors act lawfully, correct?

3 **A.** We weren't receiving suspicious orders back then.

4 **Q.** Well, I'm going to come to that point. I'm asking you  
5 a separate question, sir.

6 **A.** Okay.

7 **Q.** No distributor blocked suspicious orders before sending  
8 them prior to 2006? You don't know if that's true or false,  
9 do you?

10 **A.** I don't know if it's true or false.

11 **Q.** You can't point to any action the DEA took against any  
12 of the hundreds of distributors that were reporting and  
13 shipping prior to 2006, correct?

14 **A.** I don't recall any actions prior to 2006.

15 **Q.** You mentioned Michael Mapes several times. He was one  
16 of your colleagues at the DEA, correct?

17 **A.** Yes.

18 **Q.** And, in fact, he was responsible for training diversion  
19 investigators when you joined DEA, correct?

20 **A.** Yes, he was.

21 **Q.** He oversaw the program that trained you as a diversion  
22 investigator, correct?

23 **A.** Yes.

24 **Q.** And you have seen testimony where he said he told the  
25 plaintiff lawyers in front of you that DEA accepted

1       companies shipping and then reporting suspicious orders,  
2       correct?

3       **A.**     I saw what he said.

4       **Q.**     Yes.

5       **A.**     It was presented to me in my deposition, but I didn't  
6       agree with that.

7       **Q.**     I understand you don't agree with that, but you had  
8       seen his testimony?

9       **A.**     Yes.

10      **Q.**     Before it was presented to you, correct?

11      **A.**     I don't recall seeing his testimony before it was  
12     presented to me in deposition, no.

13      **Q.**     Let's cull up the July 16th, 2020 transcript and I'll  
14     show you what I'm talking about and, if I'm misunderstanding  
15     what you're saying, you can tell me. Page 210, Line 1 to 7,  
16     please.

17                  Do you see where I had the chance to ask you -- Line 1  
18     to 7, please. Did you see that in his testimony that he  
19     told plaintiff lawyers, including lawyers in this case, and  
20     this is a different case, that DEA accepted companies  
21     shipping and then reporting suspicious orders? Did you see  
22     that in his testimony? Answer, I saw that in his testimony.

23      **A.**     Can I see what was done before that?

24                  MR. ACKERMAN: Your Honor --

25                  THE WITNESS: Can I see the page before that, Page

1 209?

2 MR. ACKERMAN: Mr. Schmidt, can you give me the  
3 date of that deposition again?

4 MR. SCHMIDT: Yes. It's July 16th, 2020.

5 THE WITNESS: I don't want this taken out of  
6 context, so if I could look at 209, that would be great.

7 BY MR. SCHMIDT:

8 Q. My testimony is, do you see that testimony?

9 MR. ACKERMAN: Your Honor, before we go forward,  
10 is that the MDL deposition or is that Mr. Rannazzisi's  
11 expert deposition in a different case?

12 MR. SCHMIDT: It's the Ohio deposition.

13 MR. ACKERMAN: So, Your Honor, this is -- I need  
14 to make a record on this. The defendants filed a motion  
15 that said the scope of Mr. Rannazzisi's testimony is limited  
16 to information that was in his MDL depositions and we, the  
17 plaintiffs, agreed to that and that was the scope of the  
18 direct questioning. And when we went outside that scope,  
19 defendants objected.

20 This line of questioning is now concerning something  
21 that wasn't in the MDL deposition, but was in a totally  
22 separate expert deposition in another case involving the  
23 Ohio Attorney General. So, we would object to this line of  
24 questioning as outside the scope because cross examination  
25 necessarily has to be within the scope of the direct

1 examination.

2 MR. SCHMIDT: Two responses, Your Honor. This is  
3 within the scope. He testified about there not being a  
4 change in policy. He knows there was testimony from his  
5 colleagues, the very person who trained him, that there was  
6 a change in policy. So, that's an appropriate question  
7 that's well within the scope even if we were limited to the  
8 scope of his exam, which I don't believe we are. We're with  
9 a fact witness who we can't re-call in our case; but even if  
10 we were, it's well within the scope.

11 And as to the point that this is from an expert  
12 deposition, yes, it is, but this question is about his  
13 knowledge, the expertise he's claiming from being a DEA  
14 servant.

15 I'm not going to ask him about any of his expert  
16 opinions in Ohio because I agree those are off limits, but  
17 when he made factual statements, or talked about his  
18 experience, or talked about his knowledge, it's not a  
19 get-out-of-jail-free card where that's not usable. That's  
20 sworn testimony. And it's based on his experience, not  
21 based on his expert opinions in that case.

22 THE COURT: Well, this is cross examination and  
23 this is a prior statement that appears to be potentially  
24 inconsistent and I think it's fair game, Mr. Ackerman, and  
25 I'll overrule your objection.

1 BY MR. SCHMIDT:

2 Q. Do you remember showing the judge the Diversion  
3 Investigators Manual from 1997, Mr. Rannazzisi?

4 A. Yes.

5 Q. I want to come back to that. Can we put that up on the  
6 screen? It's P-8861, Page 10. And do you still -- if you  
7 need a copy, I can give you a second to find it, but I'm  
8 going to show you exactly on the screen what we're looking  
9 at. It's Page 10 of P-8861. Do you recognize this as the  
10 Diversion Investigators Manual?

11 A. I recognize it as the Diversion Investigators Manual.  
12 I don't have it in front of me.

13 MR. SCHMIDT: May I approach, Your Honor?

14 THE COURT: Yes.

15 Q. It's got a cover e-mail that looks like this. That's  
16 not going to be it. It's a half page cover e-mail. But I'm  
17 going to show it to you on the screen, so only if you need  
18 it.

19 A. Okay.

20 MR. SCHMIDT: And while we're looking for that,  
21 can we go to the next page, please, and highlight the date  
22 of this document at the bottom?

23 BY MR. SCHMIDT:

24 Q. Tell me when you're ready for me, Mr. Rannazzisi.

25 A. Here it is. We can just go off the screen. That would

1           be fine.

2       **Q.**    Okay. Do you see on Page 11 this Diversion  
3           Investigators Manual is dated April 16th, 1996?

4       **A.**    Yes.

5       **Q.**    And let's go to the language that you talked about  
6           yesterday on the next page and I want to spend a little bit  
7           more time on some of that language. Let's start with the  
8           first full sentence on the page. It says suspicious orders  
9           include those which are in excess of legitimate medical use  
10          or exhibit characteristics leading to possible diversion  
11          such as. Do you see that language?

12       **A.**    Yes.

13       **Q.**    And it then lists some of the criteria from -- or all  
14          the criteria from the suspicious order regulation?

15       **A.**    Yes.

16       **Q.**    Unusual size, unusual frequency, or those deviating  
17          from a normal pattern, correct?

18       **A.**    Yes.

19       **Q.**    And what this says is that might lead to possible  
20          diversion, correct?

21       **A.**    Yes.

22       **Q.**    It then goes on to say how the supplier, the  
23          distributor, can determine whether something is suspicious,  
24          correct?

25       **A.**    Yes.

1       **Q.**   It says the supplier can determine whether an order is  
2                   excessive. Do you see that word excessive?

3       **A.**   Yes.

4       **Q.**   By checking their own sales and establishing the  
5                   average amount of controlled substances shipped to  
6                   registrants of the same apparent size in a particular  
7                   geographic area. Do you see that?

8       **A.**   Yes.

9       **Q.**   And so, that's talking about setting a threshold as a  
10                  means of identifying suspicious orders, correct?

11      **A.**   It's one method, yes.

12      **Q.**   And it's the only method listed here, correct?

13      **A.**   Yes.

14      **Q.**   It then says that in the next sentence. If the  
15                  customer exceeds this threshold, the request should be  
16                  viewed as suspicious. Do you see that?

17      **A.**   Yes.

18      **Q.**   And to be clear, if it's -- well, let me break this  
19                  down. This is saying that if a distributor sees orders that  
20                  exceed a threshold they've set for their customers that  
21                  should be viewed as suspicious, correct?

22      **A.**   That's what it says, yes.

23      **Q.**   And that means it should be reported, correct?

24      **A.**   That means that customers should -- the distributors  
25                  should do due diligence to make the determination.

1       **Q.**    It doesn't say due diligence anywhere in here, does it?

2       **A.**    No, it does not.

3       **Q.**    If an order is, quote, "viewed as suspicious", should  
4       it be reported, yes or no?

5       **A.**    According to this, yes.

6       **Q.**    Okay. And then let's look at the next sentence,  
7       please. And let me just start on the first two words. It  
8       says this activity. Do you see those words, this activity?

9       **A.**    Yes.

10      **Q.**    This activity is an order that exceeds the threshold,  
11      correct?

12      **A.**    Yes.

13      **Q.**    And it says this activity, and I want to focus on the  
14      next clause, over extended periods of time. Do you see that  
15      language?

16      **A.**    Yes.

17      **Q.**    Would lead a reasonable person to believe that  
18      controlled substances possibly are being diverted. Do you  
19      see that language?

20      **A.**    Yes.

21      **Q.**    And so, this is saying if you see this activity,  
22      suspicious orders over extended periods of time, that  
23      activity over extended periods of time would lead a  
24      reasonable person to believe that controlled substances  
25      possibly are being diverted, correct?

1       **A.**    Yes.

2       **Q.**    Now, there's no specific language in here saying that a  
3            registrant should, quote, not fill a suspicious order,  
4            correct?

5       **A.**    I've got to read the rest of that.

6       **Q.**    Take a moment. This is an important point, sir.

7       **A.**    Well, it does later on in the paragraph.

8       **Q.**    And what does it say?

9       **A.**    As a general practice, investigation will be conducted  
10          for possible violation of the CSA and regulations upon  
11          determining that the reporting registrant, as a general  
12          practice, does not voluntarily halt shipments of controlled  
13          substances to registrants involved in suspected diversion or  
14          to registrants against whom previous action has been taken.

15      **Q.**    Okay. So, let's break that down because that's the  
16          important point. First of all, it gives us two  
17          circumstances for halting orders, correct?

18      **A.**    Yes.

19      **Q.**    One is where previous action has been taken against the  
20          registrant, correct?

21      **A.**    That's correct.

22      **Q.**    And the other is registrants involved in suspected  
23          diversion, correct?

24      **A.**    Yeah.

25      **Q.**    Those are the two instances where it says that -- where

1           it talks about voluntarily halting shipments, correct?

2       **A.**    Yes.

3       **Q.**    And let's talk about that second one, registrants  
4           involved in suspected diversion. Do you see that language?

5       **A.**    Yes.

6       **Q.**    This tells us that seeing suspicious orders over  
7           extended periods of time would lead a reasonable person to  
8           believe that controlled substances are being diverted,  
9           correct?

10      **A.**    That's what it says, yes.

11      **Q.**    There's no language in here that says that a company  
12           should not fill a single suspicious order, correct?

13      **A.**    I don't think we've ever taken action on a company that  
14           filled a single suspicious order.

15      **Q.**    Okay. And we looked at this language here about -- do  
16           you see the reference to excessive in the context of talking  
17           about setting thresholds as a trigger for reporting  
18           suspicious orders?

19      **A.**    Yes.

20      **Q.**    There's no language in here that says Excessive  
21           Purchase Reports will not be accepted, correct?

22      **A.**    It won't have to because Excessive Purchase Reports  
23           don't exist in the code or the regulations. Only Suspicious  
24           Order Reports.

25      **Q.**    When this talks about determining if an order is

1 excessive does it say anywhere in here Excessive Purchase  
2 Reports will not be accepted? Does it say that, sir?

3 **A.** No. And, in fact, we did receive Excessive Purchase  
4 Reports, but that's not a Suspicious Order Report.

5 **Q.** You've seen Mr. Mapes' sworn testimony where he said in  
6 front of you that the DEA accepted Excessive Purchase  
7 Reports as compliant with the Controlled Substances Act at  
8 least between 1997 and the distributor briefings; true?

9 **A.** No. The first time I saw that was in my deposition in  
10 the MDL. It was presented to me.

11 **Q.** Okay.

12 **A.** And I said during that deposition that I don't recall  
13 that.

14 **Q.** Okay. But you have seen that testimony from Agent  
15 Mapes, correct?

16 **A.** In my MDL deposition and I said that I didn't recall  
17 him saying that. And during that meeting, I was in and out  
18 of that meeting constantly because that was not my meeting.  
19 I was there just to make an introduction.

20 **Q.** Totally fair. You just know he's testified to that,  
21 right?

22 **A.** Yeah. After the MDL deposition.

23 **Q.** Okay. I want to look at this point we talked about, a  
24 change in policy or not a change in policy. What is the  
25 purpose of this Diversion Investigators Manual?

1       **A.**     Diversion Investigators Manual provides guidance to  
2 day-to-day operations and what they're supposed to be doing.

3       **Q.**     What they're supposed to be doing? Okay. You changed  
4 this very language we're looking at in the Diversion  
5 Investigators Manual, correct?

6       **A.**     I changed it?

7       **Q.**     Uh-huh. Did you update the Diversion Investigators  
8 Manual on your watch?

9       **A.**     The Diversion Investigators Manual was updated, yes.

10      **Q.**     All right. Let's take a look at that.

11                  MR. SCHMIDT: I'm sorry, Your Honor. May I  
12 approach? Thank you.

13                  BY MR. SCHMIDT:

14      **Q.**     So, I've given you DEF-WV-3842. It's a memorandum on  
15 the DEA letterhead dated October 27th, 2009 from you with  
16 your signature to various people, Special Agents in Charge,  
17 Diversion Program Managers, Diversion ASACs, Diversion Group  
18 Supervisors, TDS Supervisors. Do you recognize this  
19 document with your signature on it?

20      **A.**     Yes.

21                  MR. SCHMIDT: We'd move this into evidence, Your  
22 Honor, DEF-WV-3842.

23                  THE COURT: Any objection?

24                  MR. ACKERMAN: No objection.

25                  THE COURT: It's admitted.

1 BY MR. SCHMIDT:

2 Q. All right. So, let's look at what we -- what this  
3 document is doing. The first sentence of this document says  
4 the Office of Diversion Control is in the process of  
5 rewriting the diversion manual. That's the manual we were  
6 just looking at, correct?

7 A. That's correct.

8 Q. The purpose of which is to re-focus efforts within the  
9 program to ensure continued compliance among the registrant  
10 population. Do you see that?

11 A. Yes.

12 Q. And that is why you were updating the diversion manual,  
13 correct?

14 A. That and there were other things (unintelligible) --

15 COURT REPORTER: I'm sorry. Other things --

16 THE WITNESS: There were other provisions in the  
17 manual that needed to be updated because of different  
18 changes in law.

19 BY MR. SCHMIDT:

20 Q. And then the next paragraph says until such time as the  
21 manual is finalized, the attached interim guidelines will be  
22 implemented. And then you say it's the responsibility of  
23 all Diversion Program Managers and Diversion Group  
24 Supervisors to ensure the documented interim guidelines are  
25 incorporated into current and future investigations and work

1 plans upon receipt of this memorandum. Do you see that?

2 **A.** What was the question?

3 **Q.** Do you see that language?

4 **A.** Yes.

5 **Q.** And then if you look at the attachment, you did, in  
6 fact, attach the interim policy in lieu of diversion manual  
7 changes, correct?

8 **A.** Yes.

9 **Q.** This was an update to the diversion manual policies on  
10 your watch, correct?

11 **A.** Yes.

12 **Q.** All right. Let's look at these changes in the policies  
13 on your watch. Can we go to 3, please? And do you see it  
14 says suspicious order reporting? Do you see that language  
15 at the bottom of -- it's that funny thing where if you look  
16 in the lower left corner, I'm going to always be using those  
17 numbers.

18 **A.** Okay.

19 **Q.** So, it's actually Page 2 in the document, but Page 3 in  
20 the lower left corner.

21 **A.** Yeah. I've got it.

22 **Q.** And do you see where it says suspicious order  
23 reporting?

24 **A.** Yes.

25 **Q.** It states OD, that's the Office of Diversion, right?

1       **A.**     Yes.

2       **Q.**     In conjunction with CCD, has notified in writing, all  
3           distributors of their responsibility to immediately report  
4           all, quote, "suspicious orders", quote. Do you see that?

5       **A.**     Yes.

6       **Q.**     A suspicious order is an order, which, when received by  
7           a registrant and in accordance with 21 CFR 1301.74, that's  
8           the regulation you were looking at, correct?

9       **A.**     Yes.

10      **Q.**     The registrant determines to be suspicious. Do you see  
11           that?

12      **A.**     Yes.

13      **Q.**     And then it says the registrant -- and it's bolded and  
14           underlined for emphasis -- does not fill the order but  
15           reports same to their local DEA Office. Do you see that  
16           emphasized language, does not fill the order?

17      **A.**     Yes.

18      **Q.**     It then says -- that was new to this interim version of  
19           the manual, that bold underscore language, correct?

20      **A.**     Does not fill?

21      **Q.**     Yes.

22      **A.**     It's just -- it's just an update of the previous  
23           language.

24      **Q.**     That language does not appear in the prior manual as  
25           applied to a single order, correct?

1       **A.**   I would have to go back and look.

2                   MR. SCHMIDT: Why don't we -- why don't we help  
3                   Mr. Rannazzisi out. Could we do a side-by-side and can we  
4                   put P -- on the left side, could we put P-8861 on the left?  
5                   If it's possible to switch those so that P-8861 is on the  
6                   left, please.

7                   And go to Page 12 on the left, please. And if we can  
8                   blow up that language a little bit.

9                   And then on the right, can we put DEF-WV-3842, Page 3?  
10                  And if we could blow up that suspicious order reporting.

11                  And let's highlight, if we could, on the bottom does  
12                  not fill the order, singular.

13                  BY MR. SCHMIDT:

14       **Q.**   Do you see that language?

15       **A.**   Yes.

16       **Q.**   That's new to the 2009 update, correct?

17       **A.**   That's new to the manual.

18       **Q.**   Okay. And then the manual, the 2009, goes on to say  
19                  Excessive Purchase Reports from registrants, reports of  
20                  unusual size, will no longer be accepted by the DEA,  
21                  correct?

22       **A.**   That is correct, yes.

23       **Q.**   And that bold underline language in the second  
24                  sentence, will no longer be accepted, it doesn't say they've  
25                  never been accepted. It says they will no longer be

1 accepted, correct?

2 **A.** Yes. I can give you an explanation, if you would like,  
3 why it says that.

4 **Q.** And it says any firm still reporting excessive  
5 purchases. So you knew firms were doing that, right?

6 **A.** Uh-huh.

7 **Q.** Will be informed of the OD directive and instructed to  
8 immediately report, quote, "suspicious orders", quote. Do  
9 you see that?

10 **A.** Yes. And the reason that was placed there was because  
11 even after we instructed the firms in the letters and even  
12 though that we had the face-to-face meetings they were still  
13 sending Excessive Purchase Reports and we decided that  
14 instead of continuing to receive these Excessive Purchase  
15 Reports, which were not Suspicious Order Reports, and we  
16 told them those are not Suspicious Order Reports, to just  
17 stop sending the Excessive Purchase Reports totally.

18 Even though they knew that those weren't Excessive  
19 Purchase Reports they continued to send them. The only way  
20 to stop it is just to tell them to stop it. That's why that  
21 provision was put in there.

22 **Q.** That language does not appear in the Diversion  
23 Investigators Manual from before your tenure, correct?

24 **A.** It doesn't appear to appear, yes.

25 **Q.** And let's just show exactly what we're looking at in

1       the old version before, Mr. Rannazzisi. Can you highlight  
2       the supplier can determine whether an order is excessive?  
3       Starting on the sixth line, the supplier can determine  
4       whether the order is excessive. Do you see that?

5       **A.** Yes.

6       **Q.** Okay. Despite referencing the possibility of an order  
7       being excessive before your watch there's no language saying  
8       Excessive Purchase Reports will not be accepted, correct?

9       **A.** No, but the line above it talks about what suspicious  
10      orders are, which is different than excessive purchases.

11      **Q.** And then the language you have, Excessive Purchase  
12      Reports will no longer be accepted, that doesn't appear in  
13      the version of the manual before your time; is that right?

14      **A.** That's right.

15      **Q.** And then this language about does not fill the single  
16      order does not appear in the version of the manual before  
17      your watch, correct?

18      **A.** No, it does not.

19      **Q.** And what the version of the manual before your watch  
20      refers to is -- let's highlight starting on the midpoint,  
21      this activity, refers to this activity, suspicious orders,  
22      over extended periods of time, correct?

23      **A.** That's a vague statement, over extended periods of  
24      time. That could be a couple of weeks. It could be a  
25      month.

1 Q. And you took that language out in your version,  
2 correct?

3       **A.**     Yes. It was -- that was the language that was removed,  
4                   yes.

5 Q. And both of those were changes, right, to the language?

6       **A.**     Yes. It was because we were reemphasizing suspicious  
7                  orders because they weren't being followed.

8            q.        One --

9       **A.**     The suspicious order guidelines were not being  
10      followed, so we reemphasized it in the manual.

11 Q. One change in the manual is you removed any linkage  
12 between determining whether an order is excessive and  
13 exceeding a threshold being suspicious. You removed that  
14 linkage, correct?

15      **A.**    That's no longer in the 2010 manual, yes.

16 Q. And instead you changed it to say we don't accept these  
17 policies any longer, correct; these reports, I'm sorry, any  
18 longer, correct?

19           **A.**     Yes. We said that.

20 Q. And instead of talking about suspicious orders over  
21 extended periods of time leading a reasonable person to  
22 believe that controlled substances possibly are being  
23 diverted, you changed it to say the registrant does not fill  
24 the order, singular, correct?

**A.** That's correct.

1           **Q.**    Okay.

2           **A.**    Which is consistent with the letters that we sent.

3           Which is consistent with *Southwood*. Which is consistent  
4           with the distributor initiative briefings, which happened  
5           way before 2010.

6           **Q.**    Okay. I want to talk about just what you just  
7           mentioned, *Southwood*.

8           **A.**    Okay.

9           **Q.**    And this is going to seem like diversion, but it's not.  
10          You remember -- you're familiar with the *Masters*  
11          *Pharmaceutical* case, correct?

12          **A.**    Yes.

13          **Q.**    And that was a case that was being adjudicated while  
14          you were still at the DEA, correct?

15          **A.**    I think the final decision came out after I was at DEA  
16          but, yes, I was there during *Masters*.

17                    MR. SCHMIDT: May I approach, Your Honor?

18                    THE COURT: Yes, you may.

19                    MR. SCHMIDT: Thank you.

20                    BY MR. SCHMIDT:

21          **Q.**    I've passed you what I've marked as DEF-WV-2578. Do  
22          you see that this is a Federal Register entry from  
23          September 5th, 2015?

24          **A.**    Yes.

25          **Q.**    And just to be fair, the Court has seen the DC Circuit

1 appeal that followed this decision. That came after your  
2 watch. You were still at the DEA, though, on  
3 September 15th, 2015, correct?

4 **A.** Yes, but when you talked about the *Masters* decision, I  
5 was still thinking about the appellate decision.

6 **Q.** And that's why I wanted to be fair to you.

7 MR. ACKERMAN: Your Honor, I'm going to interpose  
8 a scope objection to the extent this was not at all  
9 mentioned or questioned in the MDL deposition.

10 MR. SCHMIDT: Your Honor, I don't think they get  
11 to bring a witness and ask him questions, including  
12 questions that were demonstrably outside the MDL over  
13 objection, and then shut it down on that basis.

14 THE COURT: Overruled.

15 BY MR. SCHMIDT:

16 **Q.** So, just to go back to this decision and to orient the  
17 Court to what we're talking to in that distinction between  
18 the DC Circuit decision and this decision, if you look at  
19 Page 85 of the decision, the last page, this is the decision  
20 from the DEA itself, Chuck Rosenberg, the Acting  
21 Administrator of the DEA, dated September 18th, 2018. Do  
22 you see that?

23 **A.** Yes.

24 **Q.** That came while you were still at DEA, correct?

25 **A.** Yes.

1       **Q.**   And then later, as the Court has seen, this decision  
2                  was appealed and that was after you left, the DC Circuit  
3                  decision?

4       **A.**   Yes.

5       **Q.**   Okay. So, I'll focus on this one for now.

6                  MR. SCHMIDT: And I'll move it into evidence,  
7                  DEF-WV-2578.

8                  THE COURT: Any objection?

9                  MR. ACKERMAN: I will preserve our scope  
10                 objection, but I suspect you know I know how you will rule  
11                 on that.

12                 THE COURT: Okay.

13                 MR. ACKERMAN: Can I just ask for a standing  
14                 objection on scope matters?

15                 THE COURT: Yes, you can.

16                 MR. ACKERMAN: All right. Thank you. So that  
17                 will be preserved for the record.

18                 THE COURT: Okay.

19                 MR. SCHMIDT: And, of course, we have no objection  
20                 to any standing objections and would ask for the same  
21                 courtesy to make things go fast.

22                 BY MR. SCHMIDT:

23       **Q.**   All right. Let's look at Page --

24                 MR. SCHMIDT: Sorry. Is this admitted, Your  
25                 Honor?

1                   THE COURT: Yes. It's admitted. It's admitted.

2                   BY MR. SCHMIDT:

3       **Q.** Could we go to Page 59 of the decision and let's cull  
4       out the first several lines in the upper left-hand corner.  
5       Two points on this decision.

6                   First of all, do you see that in the second line here  
7       there's reference to the Rannazzisi letters?

8       **A.** Okay.

9       **Q.** Do you see that reference?

10      **A.** Yes.

11      **Q.** And you understand that the DEA is referencing your  
12       letters from the distributor initiative, 2006 and 2007,  
13       correct?

14      **A.** I -- like I said, it's been a long time since I've seen  
15       this and, quite frankly, I have no idea what is in there.  
16       That was a long --

17      **Q.** Let's look at what they say just to answer that  
18       question. Do you see there's a reference to a 2007 letter?  
19       Do you see that?

20      **A.** Yes.

21      **Q.** And you wrote a letter on December 27th, 2007, correct?

22      **A.** Yes, I did.

23      **Q.** And that letter contained the very language on Page 2  
24       that this DEA opinion quotes as appearing on Page 2,  
25       correct?

1       **A.**     Yes.

2       **Q.**     And then they quote more and that language also is the  
3              next sentence from your letter, also on Page 2, in December,  
4              2007?

5       **A.**     Could I see --

6       **Q.**     Yes, of course. That's the end of the quote of your --  
7              of your letter. Do you see them quoting another sentence  
8              from your letter in December of 2007?

9       **A.**     Okay, I see it.

10      **Q.**     And then let's look at what they say about the letter.  
11           They say contrary to the ALJ's understanding -- you  
12           understand an ALJ is an administrative law judge, right?

13      **A.**     Yes, I do.

14      **Q.**     This simply is not language that manifests an intent to  
15           bind the agency. Do you see that language?

16      **A.**     Yes.

17      **Q.**     Do you remember giving testimony yesterday that your  
18           letters were intended to be official guidance from the DEA?

19      **A.**     Yes.

20      **Q.**     Do you know that the Administrator, the acting  
21           Administrator of the DEA, had concluded that this simply,  
22           with respect to the 2007 letter, is not language that  
23           manifests an intent to bind the agency? Did you know about  
24           that language in this decision before I showed it to you  
25           just now?

1       **A.**     No. I don't recall that language.

2       **Q.**     Let's go to the next sentence. Nor is the 2006 letter  
3           -- do you remember showing the Court the 2006 letter that  
4           you sent to all registrants?

5       **A.**     Yes.

6       **Q.**     Nor is the 2006 letter fairly read as manifesting an  
7           intent to bind the agency. Do you see that language?

8       **A.**     Yes.

9       **Q.**     And if we look further down, do you see that they  
10          actually quote Page 2, your 2006 Dear Registrant letter?

11      **A.**     Okay.

12      **Q.**     Do you see that?

13      **A.**     So, you're looking at Page --

14      **Q.**     I'm looking at this paragraph on the screen where they  
15          actually quote Page 2 of your 2006 Dear Registrant letter.

16      **A.**     Yes.

17      **Q.**     And when you testified yesterday that your letters were  
18          official guidance of the DEA, did you know that while you  
19          were there the Acting Administrator of the DEA said nor is  
20          your 2006 letter fairly read as manifesting an intent to  
21          bind the agency? Did you know that, sir?

22      **A.**     No, I didn't. This was, again, the end of my tenure.  
23          It was September when the order was released.

24      **Q.**     All right. Let's look further up this page. I'm going  
25          to ask you about one other point.

1           A review of the letters shows that they were not  
2 intended -- and we're talking about the Rannazzisi letters  
3 here. Do you see that? A review of the letters shows that  
4 they were not intended to have binding effect, but were  
5 simply warning letters. Did you know about that language  
6 before I showed it to you just now?

7       **A.** No, but those letters didn't occur under this -- that  
8 Acting Administrator. They occurred under Karen Tandy and  
9 Michelle Leonhart, who were Senate confirmed Administrators,  
10 not a -- an Acting Administrator.

11      **Q.** Go back to Page 85, please, and there you see this  
12 title that you just pointed out, Acting Administrator; do  
13 you see that?

14      **A.** Yes. Acting administrator. Not Senate confirmed.  
15 Acting Administrator.

16      **Q.** Was he in charge of the DEA at this time?

17      **A.** Yes.

18      **Q.** Was he your boss at this time?

19      **A.** Yes, he was.

20      **Q.** And I take it if you didn't know about this language  
21 you never took a public position while you were at the DEA  
22 disagreeing with this language?

23      **A.** Well, again, in September, I was on my way out. They  
24 had already replaced me at that point in time. So, no. But  
25 during my tenure, when I was in charge, those letters were

1 guidance. The Administrators, the two Administrators, knew  
2 about those letters and had no problem with those -- with  
3 those letters issued as guidance.

4 MR. SCHMIDT: And I'll move to strike his  
5 testimony about the thoughts of other -- other people.

6 THE WITNESS: Well, they were based on -- I'm  
7 sorry.

8 MR. ACKERMAN: We oppose that, Your Honor.

9 THE COURT: Well, I'll sustain that one.

10 MR. ACKERMAN: I'm sorry.

11 THE COURT: I'll grant the motion to strike that  
12 portion of his testimony.

13 BY MR. SCHMIDT:

14 Q. Now, I mentioned *Southwood*. Do you remember that?

15 A. Yes.

16 Q. *Southwood* talked about the due diligence requirement,  
17 right?

18 A. Yes.

19 Q. And that the idea of the due diligence requirement is  
20 -- it requires a registrant to first determine whether an  
21 order is suspicious and, if so, take appropriate action to  
22 dispel the suspicion before fulfilling the order, correct?

23 A. Yes.

24 Q. And that's this do not ship idea, right?

25 A. That's the do not ship.

1       **Q.**    Okay. Let's look at what this opinion from the Head of  
2           the DEA says about *Southwood*. Could we go to Page 60? And  
3           *Southwood*, to orient us, was in 2007, correct?

4       **A.**    The *Southwood* opinion was in 2007.

5       **Q.**    Okay. Let's look at what they say in the upper right  
6           corner, the first paragraph there. And we see there's some  
7           case law citation here. I'm going to go to the sentence  
8           right after that begins with "moreover" and tell me when  
9           you're there. Do you see where I'm referencing?

10      **A.**    Yes.

11      **Q.**    Okay. It says because the due diligence rule we've  
12           been discussing was announced in an adjudication, and then  
13           it goes on to say respondent was free to argue why the rule  
14           should not be applied in this matter as it was here in this  
15           matter. Do you see that?

16      **A.**    Yes.

17      **Q.**    And Mr. Reynolds has helpfully underlined this rule  
18           about due diligence being announced in an adjudication. Do  
19           you see that?

20      **A.**    Yes.

21      **Q.**    And you understand, as we see in the next sentence,  
22           that the adjudication in this opinion is saying that the due  
23           diligence decision was announced in the *Southwood* decision,  
24           correct?

25      **A.**    I'm sorry. Please repeat that. I'm trying to look at

1           this and listen at the same time.

2       **Q.**    Sure, no problem. When it says the due diligence rule  
3           was announced in an adjudication, do you see that?

4       **A.**    Yes.

5       **Q.**    That reference to an adjudication?

6       **A.**    Yes.

7       **Q.**    You understand that the adjudication being referenced  
8           is a *Southwood* decision from 2007, correct?

9       **A.**    Yes.

10      **Q.**    According to this, that's where this due diligence rule  
11           was announced, correct?

12      **A.**    Well, it was announced in a final order, yes, at that  
13           point in time.

14      **Q.**    And, in fact, you pointed distributors to the *Southwood*  
15           decision to provide them with more information about your  
16           understanding and your interpretation of the Controlled  
17           Substances Act in your second letter in 2007, correct?

18      **A.**    That's correct, December of 2007.

19      **Q.**    All right. Let's look at one more exhibit in this  
20           regard.

21                   MR. SCHMIDT: May I approach, Your Honor?

22                   THE COURT: Yes.

23                   BY MR. SCHMIDT:

24      **Q.**    This is a decision -- I'm sorry. This is the wrong  
25           one. Can I grab that back? This is the DC Circuit Masters

1 decision. I didn't mean to hand you that. I'm happy to  
2 talk about it, but it's after your time, so I didn't mean to  
3 give you that.

4 May I approach again, your Honor?

5 THE COURT: Yes.

6 MR. SCHMIDT: So, Your Honor, what I've passed the  
7 witness is an exhibit marked DEF-WV-2261. We used this with  
8 Mr. Rafalski and, at the time, I think what I proposed to  
9 the Court is that the Court could take judicial notice of  
10 it, but it didn't make sense to move it in as an exhibit  
11 yesterday, we took the decision, as an exhibit. So, I will  
12 go ahead and move this into evidence.

13 THE COURT: Any objection, Mr. Ackerman?

14 MR. ACKERMAN: Yes. I think the decision that was  
15 taken as an exhibit was an ALJ decision and, therefore, was  
16 a public record and taken as evidences of notice. I don't  
17 think we would agree that a court decision is appropriate as  
18 evidence.

19 THE COURT: Well, what about it, Mr. Schmidt?

20 MR. SCHMIDT: I think it's a government record.  
21 It is a literal definition of a governmental record and I  
22 think there's --

23 THE COURT: Well, I can take judicial notice.

24 MR. SCHMIDT: And you can take judicial notice.

25 THE COURT: It's admitted, Mr. Ackerman.

1                   MR. ACKERMAN: Your Honor, can I clarify something  
2 for the record because --

3                   THE COURT: Mr. Schmidt, let's --

4                   MR. SCHMIDT: Sorry.

5                   MR. ACKERMAN: I think he was just asking Mr.  
6 Rannazzisi if he needed water.

7                   I just wanted to clarify something for the record  
8 because this is an issue that has come up several times. I  
9 think it came up with direct sales. I think it came up  
10 other times in this litigation. If the Court is going to be  
11 accepting -- there were instances where the Court did not  
12 accept judicial decisions as evidence or exhibits in this  
13 case.

14                  And so, if that -- if the Court is going to adopt a  
15 different practice at this time, that's perfectly within the  
16 Court's discretion. I just want to make it clear because I  
17 know this is an issue likely in deposition designation  
18 exhibits to objections and elsewhere.

19                  THE COURT: Well, I'm not sure I understand why  
20 there's an issue about this.

21                  MR. ACKERMAN: So, the decision that we moved in  
22 yesterday was *Southwood Pharmaceuticals*, which was from the  
23 DEA website, and it was in the Federal Register like this  
24 *Masters* decision. I understand.

25                  These are court decisions. They're not -- they can't

1       be admitted for the truth. I -- I'm certainly not going to  
2       question that a judge is not reliable, but we have heard  
3       from defendants over and over again in this trial that  
4       judicial opinions aren't evidence.

5           So, I don't understand the purpose for which they're  
6       being offered and I believe the Court has rejected earlier  
7       attempts to put judicial opinions in as evidence.

8           MR. SCHMIDT: And Mr. Ackerman is right. We have  
9       objected. We've taken the position that they're notice with  
10       change. And the reason I move this in now and not before is  
11       yesterday the Court admitted the *Southwood* decision. Our  
12       view is that's exactly the same principle subject to  
13       judicial notice.

14           Frankly, I don't think we have a strong view either  
15       way, but if some key opinions are going in the record, we  
16       think this is a key opinion that should go in the record. I  
17       think it's a little bit of an academic dispute and, on my  
18       part, is prompted only by *Southwood* going in yesterday and  
19       I'm wanting to make sure that the Court has access readily  
20       in an easy form in the record to what we're talking about.

21           But I do think the point is right. The Court can take  
22       notice. So, whichever the easiest way to deal with it is,  
23       I'm fine with proceeding. It's something that's before the  
24       Court. I think the Court has taken judicial notice of this  
25       decision. I don't think any of these materials need to be

1       in the record in terms of the *Southwood* decision yesterday,  
2       but if we are admitting them, it makes sense to treat them  
3       the same.

4                   THE COURT: Well, what -- what is the purpose that  
5       it's admitted? It's not coming in for the -- just tell me  
6       what the -- what the purpose of it as evidence is.

7                   MR. SCHMIDT: The purpose of it as evidence is it  
8       documents sworn testimony in the case from Mr. Rannazzisi's  
9       colleagues on his watch while he was at DEA on relevant  
10      points in this litigation.

11                  THE COURT: Well, you could use it as a basis to  
12      ask him about that without admitting it, couldn't you?

13                  MR. SCHMIDT: Yes, but I think if we're going to  
14      admit some decisions like *Southwood* from yesterday, the  
15      better course is to admit this.

16                  THE COURT: Mr. Ackerman?

17                  MR. ACKERMAN: The distinction, Your Honor, that  
18      we have made is that we admitted *Southwood* as notice to the  
19      defendants. This is not being offered for notice. It's  
20      being offered essentially for the truth of the matter  
21      asserted therein.

22                  MR. SCHMIDT: *Southwood* was not admitted under a  
23      limited basis.

24                  MR. ACKERMAN: And it was a public record of the  
25      DEA, not of a -- this is --

1                   MR. SCHMIDT: A public record of the United States  
2 Judiciary, Article III of the Constitution.

3                   MR. ACKERMAN: I'm going back to my rules, Your  
4 Honor. 803(8) says a record or statement of public office,  
5 and I don't know whether the Judiciary in and of itself is a  
6 public office. I am just going to say that's what the rule  
7 says.

8                   THE COURT: I don't understand why there's a big  
9 argument about this when it's a matter that -- a public  
10 record that the Court could take judicial notice of. Why  
11 does it have to be admitted as evidence or not as admitted  
12 as evidence?

13                  MR. SCHMIDT: That's what I was going to say.  
14 With that statement from the Court, I'll just question on it  
15 and I'll -- I'll move on.

16                  BY MR. SCHMIDT:

17                  **Q.** You have in front of you DEF-WV-2261.

18                  **A.** Yes.

19                  **Q.** And do you understand that this is a decision involving  
20 the United States while you were at DEA from the Eastern  
21 District of Michigan in 2012?

22                  **A.** Yes.

23                  **Q.** And do you have the understanding from seeing this  
24 decision before, and I can point you to a specific portion  
25 of the opinion, that it reflects testimony from people in

1       your office, Kyle Wright, Michael Mapes, James Rafalski,  
2       under your supervision as Head of the Office of Diversion  
3       Control?

4       **A.**     I seem to remember Kyle Wright. I didn't know Mike  
5       Mapes was involved in this.

6       **Q.**     Okay. And let me actually correct. I'm not sure if he  
7       gave testimony, but he's quoted in the opinion. So, let's  
8       look at Page 6 of the opinion, please. If we could cull out  
9       the third paragraph, please.

10           It says the government offered testimony that the DEA  
11       sought to expand drug wholesalers' obligations by a policy  
12       change in 2006 and 2007, although there was never a change  
13       to the regulations.

14           THE COURT: Mr. Ackerman?

15           MR. ACKERMAN: Objection, Your Honor, and this is  
16       the problem that we get into. This is several levels of  
17       hearsay because this is now the Court saying that the  
18       government said something. We don't have any access to the  
19       record in this case. If there was testimony by the  
20       government, it's something that we can assess, but at this  
21       point, we're now cross examining based on the two or three  
22       levels of hearsay.

23           THE COURT: He's offering this as evidence. If I  
24       understand what's going on here, he's offering -- he's using  
25       it as a good faith basis to cross-examine the witness and

1 it's perfectly proper for that purpose.

2 MR. SCHMIDT: And just for the record, you do have  
3 the testimony from this case. We've used it in depositions  
4 with Mr. Rafalski.

5 THE COURT: Overruled. You can go ahead, Mr.  
6 Schmidt.

7 BY MR. SCHMIDT:

8 Q. Do you see this language about testimony from  
9 government officials that the DEA sought to expand drug  
10 wholesalers' obligations by a policy change in 2006 and  
11 2007, although there was never a change to the regulations?  
12 Do you see that?

13 A. I see that, yes.

14 Q. And the point about there was never a change to the  
15 regulations, that's true, right?

16 A. There was not a change to the regulations, no.

17 Q. And whatever testimony was offered in this case from  
18 DEA officials came from DEA officials you supervised,  
19 correct?

20 A. Well, if it's Kyle Wright, yes. He was under my  
21 supervision.

22 Q. And, in fact, just so we're clear, at one point, you  
23 were going to give testimony in this case, correct, but  
24 because of a kind of timing issue as to when your disclosure  
25 was made, you weren't able to give testimony, correct?

1       **A.**    That's correct.

2       **Q.**    Okay. One of the changes -- I think you were going to  
3           give expert testimony, correct?

4       **A.**    I was going to give testimony on the suspicious order  
5           monitoring requirements.

6       **Q.**    Okay. One of the changes in interpretation by the DEA  
7           concerned the circumstances under which a distributor should  
8           suspend shipments to a customer if it identified the  
9           customer -- if it identified an order as suspicious. Do you  
10          see that?

11       **A.**    Yes.

12       **Q.**    And that's the do not ship policy you understand being  
13          referenced there?

14       **A.**    Yes.

15       **Q.**    That change in policy apparently prompted concern  
16          within the DEA compliance sectors that confusion would  
17          result since the prior report-only policy had been in place  
18          for 35 years and then it refers to DEA personnel began to  
19          conduct distributor briefings to familiarize drug  
20          wholesalers with the new policy. Do you see that?

21       **A.**    Yes.

22       **Q.**    And you understand from the time period that those  
23          distributor briefings are the same ones we've been talking  
24          about throughout your testimony, correct?

25       **A.**    Yes.

1       **Q.**     Goes on to say Kyle Wright, who you supervised, it says  
2     DEA began to conduct distributor briefings to -- I'm sorry.  
3     Kyle Wright, the Unit Chief of the E-commerce section at the  
4     Office of Diversion Control at the DEA Headquarters in  
5     Washington, D.C. in 2006 and 2007, testified that he played  
6     an important role in developing the briefings. Do you see  
7     that?

8       **A.**     Yes.

9       **Q.**     Is that true?

10      **A.**     Yes.

11      **Q.**     Let's go to the next paragraph. In all events, Wright  
12     testified that the DEA was aware that it was standard  
13     practice in the industry to file Suspicious Order Reports  
14     while continuing to ship products, and that practice had  
15     been approved by the DEA. Do you see that?

16      **A.**     Yes.

17      **Q.**     Do you recall me asking you yesterday about the fact  
18     that there was a window, I think, between 19 -- I'm going to  
19     get the years wrong, is it '88 and 2005, where you didn't  
20     deal with distributors? Do you remember that?

21      **A.**     Yes.

22      **Q.**     Mr. Wright was dealing with distributors before 2005,  
23     correct?

24      **A.**     Yes.

25      **Q.**     And then here's where I might have gotten tripped up.

1 Let's go to the next paragraph, please. In the second  
2 sentence, it says Wright's supervisor, Michael Mapes, told  
3 distributors at the DEA's Pharmaceutical Industry Conference  
4 on September 11th, 2007 that the DEA's new interpretation of  
5 the suspicious order regulation was that distributors should  
6 suspend shipments if they routinely report suspicious orders  
7 with reason to believe they are destined for the illicit  
8 market. Do you see that?

9 **A.** I see that.

10 **Q.** Did you attend that conference with Mr. Mapes?

11 **A.** No, I did not.

12 **Q.** Did you issue any public statements disagreeing with  
13 this decision when it came out in 2012 on your watch?

14 **A.** No, I did not.

15 **Q.** I want to go back to reports that were made before 2008  
16 and you talked about that term "Excessive Purchase Reports";  
17 do you recall that?

18 **A.** Yes.

19 **Q.** Do you know that McKesson believed it was making  
20 Suspicious Order Reports before that period?

21 **A.** Yes.

22 **Q.** And let's look at what we're -- let's show the judge  
23 what we're talking about.

24 **A.** Suspicious or excessive?

25 **Q.** Suspicious.

1       **A.**     I don't know if -- what McKesson believed or what they  
2     didn't believe, to be honest with you.

3       **Q.**     Okay, fair enough. They told the DEA they were making  
4     suspicious reports, correct?

5       **A.**     I'm not aware of them telling the DEA that they made  
6     suspicious reports.

7       **Q.**     Okay. Do you have that massive set of reports --

8       **A.**     Yes.

9       **Q.**     -- 42747 in front of you?

10      **A.**     Yes.

11      **Q.**     And if we go to the second page of that document, and  
12     if we look at the heading where it says "McKesson  
13     Corporation".

14      **A.**     Okay.

15      **Q.**     Do you see right under there it says Monthly Controlled  
16     Substance Order Report? Do you see that?

17      **A.**     Yes.

18      **Q.**     Okay. And then let's look down at this language here  
19     and this is what I want to focus on. Pursuant to CFR 21  
20     Section 1301.74(B). Do you see that?

21      **A.**     Yes.

22      **Q.**     Is that the regulation we were looking at that is the  
23     suspicious order regulation?

24      **A.**     Yes.

25      **Q.**     So, they say pursuant to the suspicious order

1 regulation we are sending a copy of the Monthly Controlled  
2 Substance Order Report for September, '09. Do you see that?

3 **A.** Yes.

4 **Q.** And then do you remember saying that they never  
5 explained why --

6 **A.** Yes.

7 **Q.** -- they were flagging the orders?

8 **A.** Uh-huh.

9 **Q.** Let's look at the explanation. It says this report  
10 reflects purchases from customers for Schedules II-V,  
11 controlled substances which exceed the item monthly average  
12 for the class of trade. Do you see that?

13 **A.** Yes.

14 **Q.** And remember the Diversion Investigators Manual we've  
15 looked at that talked about exceeding thresholds?

16 **A.** Yes.

17 **Q.** This is telling DEA that the way these are identified  
18 is they exceed the item monthly average for the class of  
19 trade, correct?

20 **A.** That's what it says, but that's still not a suspicious  
21 order.

22 **Q.** If we go on, it says a listing of the parameters used  
23 are available upon request. Do you see that?

24 **A.** Yes.

25 **Q.** Were they ever requested, to your knowledge? Do you

1 know?

2 **A.** I don't know. But, again, this is not a suspicious  
3 order. First of all, this is monthly. It's supposed to be  
4 done when discovered. And you're supposed to have a  
5 description of why it's suspicious, not just that it  
6 breached threshold.

7 You're supposed to talk about the pharmacy. Explain  
8 why this pharmacy is doing something suspicious. Not just  
9 -- not just, oh, they were above threshold. That means  
10 nothing to us.

11 **Q.** Let's go back to DEF-WV-640. Do you remember this  
12 language in the regulation?

13 **A.** Yes.

14 **Q.** Where does it say in there you've got to tell us about  
15 the pharmacy or why you say it's suspicious?

16 **A.** It doesn't. It says it in the letters that we wrote  
17 providing guidance.

18 **Q.** Is there a letter you wrote that says you need to tell  
19 us information about this pharmacy?

20 **A.** It says that you have to explain why an order is  
21 suspicious. Just being over threshold is not suspicious.

22 **Q.** When did you write that letter?

23 **A.** I think 2006 and -- one of the 2006 or 2007 letters,  
24 one of those letters has it. It was also described in the  
25 distributor briefings.

1       **Q.**    Which you didn't attend?

2       **A.**    That I didn't attend, that's exactly right.

3       **Q.**    I'll come back to that. Let's go back to the report.

4       **A.**    Okay.

5       **Q.**    Sorry. 42747, Page 2, please, back to the report that  
6       you looked at for counsel for the plaintiffs.

7       **A.**    Yes.

8       **Q.**    And I want to focus again on this language, a listing  
9       of parameters used are available upon request. Do you see  
10      that?

11      **A.**    Yes.

12      **Q.**    Do you know how many times during audits,  
13      registrations, otherwise, DEA officials looked at the  
14      parameters that were used to determine whether this report  
15      that McKesson was making pursuant to the suspicious order  
16      regulation, how those worked? Do you know how many times  
17      DEA agents looked at those?

18      **A.**    No, sir, I don't.

19      **Q.**    All right. Let's go back to DEF-WV-1549. Just to be  
20      clear, could we go back to 42747? And I just want to be  
21      absolutely clear for the record on this in case I didn't get  
22      it.

23                  If we could highlight that language pursuant to 21 C.  
24                  F. R. 1301.74(B).

25                  Do you see that language?

1       **A.**     Yes.

2       **Q.**     Let's go back to DEF-WV-640. This is the suspicious  
3           order regulation, 1301.74(B), that we've been talking about  
4           that McKesson told the DEA was the basis for it making those  
5           reports, correct?

6       **A.**     Yes.

7       **Q.**     Okay. So, let's look at the letter that we talked  
8           about a little bit yesterday. I want to finish up with this  
9           letter from January 23rd, 2006, the DEA memo to you from Mr.  
10          Mapes, dated -- Bates stamped -- exhibit stamped  
11          DEF-WV-1549. Do you remember talking about this letter?

12       **A.**     Yes. I'm trying to find it.

13       **Q.**     And if we go to the second page, I want to just blow up  
14          the pharmacies being discussed here.

15       **A.**     Yes.

16       **Q.**     And you recall we talked a little bit about these six  
17          pharmacies that the DEA identified based on ARCos data,  
18          correct?

19       **A.**     That's correct.

20       **Q.**     And they were identifying generic and branded  
21          hydrocodone sales, correct?

22       **A.**     I'm sorry. Who was --

23       **Q.**     The DEA. These numbers included generic and branded  
24          hydrocodone numbers, correct?

25       **A.**     Yes.

1       **Q.**   And that came from the ARCos data that McKesson  
2                  reported to the DEA, correct?

3       **A.**   Yes.

4       **Q.**   McKesson was reporting both generic data and branded  
5                  data, correct?

6       **A.**   Yes.

7                  MR. SCHMIDT: May I approach, Your Honor?

8                  THE COURT: Yes.

9                  BY MR. SCHMIDT:

10      **Q.**   I've passed you something marked MC-WV-2143 and let's  
11                  go to the second page. Do you see that this is the type of  
12                  DU45 report that you said you had seen at the DEA?

13      **A.**   I believe I saw this report at one point in time, yes.

14      **Q.**   Okay. Let's look at what it says.

15                  MR. SCHMIDT: I'll move it into evidence on that  
16                  basis, Your Honor.

17                  THE COURT: Any objection?

18                  MR. ACKERMAN: No objection.

19                  THE COURT: It's admitted.

20                  BY MR. SCHMIDT:

21      **Q.**   If we look at the top, do you see where it says Daily  
22                  Controlled Substance Suspicious Purchase Report? Do you see  
23                  it refers to a daily report?

24      **A.**   Yes.

25      **Q.**   And if we look in the upper left-hand corner, it gives

1 us the date -- sorry. It gives us the date that this  
2 particular report was run, November 25th. Do you see that?

3 **A.** Yes. And then if we look down, it has reports from  
4 earlier dates included.

5 MR. SCHMIDT: Can you take that down?

6 BY MR. SCHMIDT:

7 **Q.** Going all the way back to November 7th. Do you see  
8 that?

9 **A.** Yes.

10 **Q.** And if you look at that language we looked at in the  
11 other document right here, do you see that it again  
12 references the suspicious order regulation of 21 CFR  
13 1301.74 (B) ?

14 **A.** Yes.

15 **Q.** Do you see it says we are sending a copy of the Daily  
16 Controlled Substance Suspicious Purchase Report for  
17 November 25th, 2005?

18 **A.** Yes.

19 **Q.** And that it again says we picked it based on exceeding  
20 the item monthly average listing the parameters used are  
21 available upon request. Do you see that?

22 **A.** Yes.

23 **Q.** All right. Let's see if we can put on the left-hand  
24 side of the screen DEF-WV-1549 and on the right-hand side of  
25 the screen the document we currently have up.

1           And what I would like to do on the left side is on Page  
2 2. So, just to orient us, on the left side, we have the  
3 memo you received in January of 2006 reflecting the  
4 discussion with McKesson, correct?

5 **A.** Say that again.

6 **Q.** On the left-hand side we have the memo you received in  
7 January, 2006 reflecting the discussion with McKesson?

8 **A.** Yes.

9 **Q.** And it lists the six pharmacies that were raised with  
10 McKesson at that January meeting?

11 **A.** Yes.

12 **Q.** Let's look at the first one of those pharmacies.

13           MR. SCHMIDT: Could you highlight on the left  
14 AccuMed just down at the bottom?

15           BY MR. SCHMIDT:

16 **Q.** Do you see AccuMed at the bottom of the memo as one of  
17 the six pharmacies that was discussed?

18 **A.** Yes.

19 **Q.** And do you see on the right, if we go to Page -- I'm  
20 sorry. I think I skipped us ahead.

21           MR. SCHMIDT: Just to make it easier, could you  
22 highlight MediPharm?

23           BY MR. SCHMIDT:

24 **Q.** Do you see MediPharm is one of the pharmacies that was  
25 discussed in the January meeting with McKesson?

1       **A.**     Yes.

2       **Q.**     If we look on the right, do you see that this is,  
3                   according to the document at least, a Daily Controlled  
4                   Substance Suspicious Purchase Report for MediPharm from  
5                   November of 2005? Do you see that?

6       **A.**     Yes.

7       **Q.**     Okay. And if we look down on the form --

8                   MR. SCHMIDT: Can we go to Page 8, please? On the  
9                   right. I'm sorry. Let's go to the next one.

10                  BY MR. SCHMIDT:

11       **Q.**     Do you see that Page 8 is AccuMed? Do you see that?

12       **A.**     Yes.

13       **Q.**     And do you see that AccuMed is another one of the  
14                   pharmacies listed in your letter?

15       **A.**     Yes.

16       **Q.**     And if we take down that AccuMed cull-out, do you see  
17                   that under the AccuMed listing there are listings for a  
18                   product called Norco, which is a branded prescription  
19                   opioid? Do you see that? It's a little bit hard to read,  
20                   but do you see that reference to the branded products?

21       **A.**     Yes.

22       **Q.**     And then there's a reference below to generic  
23                   hydrocodone, correct?

24       **A.**     Yes.

25       **Q.**     And these reports that McKesson was making pursuant to

1       the suspicious order regulation included branded products  
2       and generic products, correct?

3       **A.**     Yes.

4       **Q.**     All right. And just -- we'll do this as quickly as  
5       possible.

6                   MR. SCHMIDT: Could we put up -- we've done  
7       MediPharm. We've done AccuMed. Could we put up Page 5 on  
8       the right?

9                   BY MR. SCHMIDT:

10      **Q.**     Do you see that this is Bi-Wise report on Page 5?

11      **A.**     Yes.

12      **Q.**     And do you see Bi-Wise is another one of the six  
13       pharmacies on Page -- on your January memo?

14      **A.**     Yes.

15                   MR. SCHMIDT: Let's put up Page 21 on the right.

16                   BY MR. SCHMIDT:

17      **Q.**     Do you see that this is of Avee Pharmacy with reports  
18       made pursuant to the suspicious order regulation on the  
19       right, Page 21?

20      **A.**     Okay.

21      **Q.**     And Avee is another pharmacy mentioned in your memo in  
22       January, two months later, correct?

23      **A.**     Yes.

24      **Q.**     Let's go to Page 25. Do you see that there's Universal  
25       Rx on the right with reports pursuant to the suspicious

1           order regulation?

2       **A.**    Yes.

3       **Q.**    And do you see that on the left that's another one of  
4           the pharmacies mentioned? Do you see that?

5       **A.**    Yes.

6       **Q.**    And last one, Page 48 on the right, United Prescription  
7           Services, also reports from November, 2005. Do you see  
8           that?

9       **A.**    Yes.

10      **Q.**    And they're also one of the pharmacies discussed on the  
11           left. Do you see that?

12      **A.**    Yes.

13      **Q.**    And so we know from looking at this that McKesson's  
14           data as it provided it to the DEA -- and ARCOS identified  
15           generic and branded data, correct?

16      **A.**    Yes. It looks that way, yes.

17      **Q.**    And in these reports made pursuant to the suspicious  
18           order regulation, they've identified generic and branded  
19           data, correct?

20      **A.**    Well, these reports aren't made pursuant to suspicious  
21           order. They weren't reported as discovered. Some of these  
22           reports -- if you go by the fax sheet here, some of these  
23           reports were three, four days after the fax sheet. Some of  
24           these reports happened -- the fax sheet is dated 1/28. Some  
25           of these reports are -- or 11/28. Some of these reports are

1 after 11/29. So, if the fax sheet is dated 11/28, how could  
2 they possibly be reported the day after the fax was actually  
3 faxed?

4 **Q.** If you flip through that document, do you see there are  
5 multiple fax sheets in there?

6 **A.** No. I didn't see multiple fax sheets. Okay. I found  
7 one. But still --

8 **Q.** Let me address your other point, if I could, Mr.  
9 Rannazzisi.

10 **A.** Yeah.

11 **Q.** Did you know these were rolling reports, so that when  
12 they made the daily report, they provide the previous  
13 reports made for that pharmacy in a month? Do you know  
14 whether that was the case or not?

15 **A.** No. I don't know whether that was the case.

16 **Q.** Let me go back to my question and let's cull out this  
17 language pursuant to CFR Section 1301.74(B), right?

18 **A.** Yeah.

19 **Q.** McKesson said it was providing DEA with reports  
20 pursuant to the suspicious order regulation that covered  
21 both generic and branded opioids, correct?

22 **A.** It looks that way, yes, in these reports, yes.

23 **Q.** Now, I touched yesterday on changes McKesson made to  
24 its suspicious order monitoring policy in response to some  
25 of these discussions in 2005 and 2006 with the DEA about

1       these pharmacies in Florida. Do you remember touching on  
2       that briefly yesterday afternoon?

3       **A.**     Could you repeat the question, please?

4       **Q.**     Sure. And why don't I just go to the meat of it. Are  
5       you aware that following discussions with the DEA in 2005  
6       and 2006, McKesson twice updated its policies regarding  
7       suspicious order monitoring?

8       **A.**     Yes. I was told that they did their suspicious order  
9       monitoring, yes.

10      **Q.**     Let's go ahead. I'm going to pass out Exhibit  
11      DEF-WV-1527.

12                  MR. SCHMIDT: May I approach with that, Your  
13                  Honor?

14                  BY MR. SCHMIDT:

15      **Q.**     And this is a letter on the cover written for -- from  
16       counsel for McKesson, June 12th, 2007, to Linden Barber,  
17       Office of Chief Counsel at the Drug Enforcement  
18       Administration. You know Mr. Barber, correct?

19      **A.**     Yes, I do.

20      **Q.**     He was a former colleague of yours at the DEA, correct?

21      **A.**     Yes.

22      **Q.**     And if we look down, he says I have attached a copy of  
23       the following information: Amendment to the McKesson DC  
24       Operations Manual describing the standard operating  
25       procedures for the lifestyle Drug Monitoring Program and

1       then a PowerPoint presentation on that program. Do you see  
2       that?

3       **A.**     Yes.

4       **Q.**     Is that one of the policies that you were told, one of  
5       the policy changes McKesson made following these discussions  
6       about these pharmacies in this 2005, 2006, 2007 time period?

7       **A.**     I can't tell you exactly, but I was told that they  
8       changed their -- their Suspicious Order Monitoring Program  
9       policies, but I -- I can't remember what I was told.

10      **Q.**     Okay. So, if we go --

11                  MR. SCHMIDT: I'll move this into -- into  
12                  evidence. It's on the stipulation.

13                  THE COURT: Any objection?

14                  MR. ACKERMAN: No objection, Your Honor.

15                  THE COURT: All right. It's admitted.

16                  MR. SCHMIDT: May I confer for just one moment?

17                  (Pause)

18                  BY MR. SCHMIDT:

19       **Q.**     Do you see that if we go to Page 3 of this document  
20       there actually is a copy of the Lifestyle Drug Monitoring  
21       Program being referenced? Do you see that?

22       **A.**     Yes.

23       **Q.**     And then if you go to Page 10 of the document, there's  
24       a copy of those PowerPoint slides from Mr. Walker, Senior  
25       Vice President Distribution Operations that's referenced?

1           **A.** Yes.

2           **Q.** Did you ever review those materials when you were at  
3           DEA?

4           **A.** No.

5           **Q.** Are you aware of anyone raising concerns about this  
6           policy when it was sent to your colleagues at DEA?

7           **A.** I -- I'm sure they would have had -- they would have  
8           had concerns about it, but it wasn't brought to my  
9           attention.

10          **Q.** Are there any you can point me to that you know about  
11           factually?

12          **A.** That was told to me? No.

13                   MR. SCHMIDT: And then one more document in this  
14           area and then this may be a good time for a break, Your  
15           Honor.

16                   May I approach again?

17                   THE COURT: Yes.

18                   BY MR. SCHMIDT:

19          **Q.** Are you aware that in 2008 McKesson adopted a policy  
20           called the Controlled Substance Monitoring Program?

21          **A.** Yes.

22          **Q.** And this document is in evidence, McKesson West  
23           Virginia 397. Are you aware that Don Walker, the person we  
24           just spoke about from McKesson, came in and gave a  
25           presentation on the Controlled Substance Monitoring Program

1 and provided a copy of that policy to your colleagues at the  
2 DEA?

3 **A.** No, I'm not aware of that.

4 **Q.** Okay.

5 **A.** I mean, I'm sure I was told about it, but I can't give  
6 you any information about that meeting.

7 **Q.** There's no objections you can tell me or concerns that  
8 anyone at DEA raised in response to the presentation or the  
9 policy, correct?

10 MR. ACKERMAN: To his knowledge, right?

11 BY MR. SCHMIDT:

12 **Q.** To your knowledge, of course?

13 **A.** To my knowledge, no.

14 MR. SCHMIDT: And then I can stop here or I can do  
15 two more minutes, Your Honor. Up to the Court. Probably  
16 like five more minutes.

17 THE COURT: I think this a good place to stop, Mr.  
18 Schmidt. We'll be in recess for 10 to 15 minutes.

19 (Recess taken)

20 (Proceedings resumed at 10:30 a.m. as follows:)

21 MR. SCHMIDT: May I proceed, Your Honor?

22 BY MR. SCHMIDT:

23 **Q.** Mr. Rannazzisi, are you good to proceed?

24 **A.** Yes, sir.

25 **Q.** Thank you, sir. I'd like to continue with one more

1 point on McKesson.

2 Let's take a look at the 2008 Settlement Agreement that  
3 you talked about with counsel, P-23736. Tell me when you're  
4 ready to testify about that.

5 **A.** You can go ahead.

6 **Q.** Do you recall being asked yesterday about this  
7 agreement covering Lakeland, Landover, Conroe, and Denver in  
8 terms of those distribution centers?

9 **A.** Yes.

10 **Q.** Are you aware that none of those distribution centers  
11 regularly service Huntington and Cabell County?

12 **A.** I -- that I don't know.

13 **Q.** Okay. Fair enough. Do you know that the Washington  
14 Court House distribution center does regularly service  
15 Huntington and Cabell County?

16 **A.** Again, if you're asking me back then, I did not know.

17 **Q.** Okay. You understand that Washington Court House isn't  
18 mentioned in this agreement?

19 **A.** I don't believe Washington Court House is mentioned.

20 **Q.** You talked about yesterday about how many distribution  
21 centers the distributors have. How many does McKesson have?

22 **A.** I believe from yesterday 27, 26.

23 **Q.** Okay. Let's take 26. Four out of 26 -- when you gave  
24 testimony yesterday about this, whether this was or was not  
25 a systemic issue, the distribution centers covered by this

1 agreement are less than 20 percent of the 26 distribution  
2 centers you just referenced; correct?

3 **A.** We don't look at it that way.

4 **Q.** Okay.

5 **A.** The way --

6 **Q.** Am I right or am I not?

7 **A.** 20 percent, but that's a lot of diversion occurring.

8 20 percent -- these are big facilities that treat a lot of  
9 pharmacies, distributes to a lot of pharmacies.

10 **Q.** Okay. Let's go to the second page. Just so we have  
11 it, you understand that this agreement contains no admission  
12 or concession; correct?

13 **A.** Yes.

14 **Q.** Let's go to -- well, actually, before I go on in this,  
15 there was no immediate -- I believe you testified to this.  
16 There was no Immediate Suspension Order issued by the DEA  
17 leading up to this Settlement Agreement; correct?

18 **A.** I'd have to go back and look, but I don't recall -- I  
19 don't recall an Immediate Suspension Order. There may have  
20 been. I just don't recall.

21 **Q.** Okay.

22 **A.** I know there was Orders to Show Cause. There were at  
23 least four orders -- or three Orders to Show Cause.

24 **Q.** And we saw those and we see those referenced in the  
25 agreement; correct?

1       **A.**     Yes.

2       **Q.**     And there's no reference and no recollection you have  
3                  of an Immediate Suspension Order; correct?

4       **A.**     No, not that I -- I don't recall an Immediate  
5                  Suspension Order. I just recall the Orders to Show Cause.

6       **Q.**     And DEA would issue an Immediate Suspension Order when  
7                  you were at DEA if there was an imminent danger to the  
8                  public health or safety; correct?

9       **A.**     That's correct.

10      **Q.**     Let's turn to Page 4. And this is in the section that  
11                talks about obligations of McKesson. And this is language I  
12                think you were shown yesterday.

13                If we go to (e), "McKesson agrees that any express or  
14                implied approval by DEA of any previously implemented system  
15                to detect and report suspicious orders is hereby rescinded  
16                and is of no legal effect."

17                Do you see that language?

18       **A.**     Yes.

19      **Q.**     Am I correct that you saw a need to write into this  
20                agreement that any prior approvals, express or implied, by  
21                DEA were rescinded?

22      **A.**     Yes. We put that in there because, again, the industry  
23                as a whole felt there were approved systems and we wanted to  
24                make sure that was correct.

25      **Q.**     And we talked about how you came into Diversion Control

1       in 2005; correct?

2       **A.**    That's correct.

3       **Q.**    Just "yes" or "no" have you seen documents that led  
4           defendants, including McKesson, to believe that their  
5           systems had been approved prior to that time?

6       **A.**    No, I don't believe I have seen a document.

7       **Q.**    Okay. Let's go on to Page 6, please. And you were  
8           shown -- well, let's start with (e). Do you see that it  
9           says, "Within 150 days of the effective date of this  
10          agreement, but not earlier than 90 days after the effective  
11          date of this agreement, DEA shall conduct reviews of the  
12          functionality of McKesson's diversion compliance program at  
13          up to eight distribution centers of McKesson."

14           Do you see that language?

15       **A.**    Yes.

16       **Q.**    And you understand that when this is talking about  
17          conducting reviews of the functionality of McKesson's  
18          diversion compliance program, it's talking about that CSMP  
19          that we referred to before the break?

20       **A.**    Whatever system was in place at that time.

21       **Q.**    And do you take issue with the CSM -- with the  
22          testimony the Court has heard about the CSMP being in place  
23          at that time?

24       **A.**    No, I don't take issue with it. I'm just saying  
25          whatever system we had in place at that time.

1       **Q.**    Got it. And you would -- if we look at this section,  
2                  this section appears in a portion of the report if you want  
3                  to look back at Page 5.

4                  Let's put it up on the screen for just a second.

5                  This appears in the section of the report talking about  
6                  the obligations of the DEA. Do you see that?

7       **A.**    Yes.

8       **Q.**    So let's go back to Page 6. Would you expect the DEA  
9                  to meet their obligation to conduct reviews of the  
10                 functionality of McKesson's diversion compliance program?

11      **A.**    Yes.

12      **Q.**    All right. The next sentence says, "DEA shall also  
13                 review the investigatory files maintained by McKesson of the  
14                 customers serviced by the distribution centers subject to  
15                 the compliance reviews."

16                  And let's just underline "review the investigatory  
17                 files" if we could at the end of the second highlighted line  
18                 from the bottom where it says "review the investigatory  
19                 files."

20                  Would you expect the DEA to meet their obligation to  
21                 review the investigatory files maintained by McKesson of the  
22                 customers serviced by the distribution centers subject to  
23                 the reviews?

24      **A.**    Yes.

25      **Q.**    It goes on. Let's skip a sentence. It says, "During

1       the course of the compliance review, if requested McKesson  
2       shall provide DEA with information related to the sales of  
3       controlled substances, non-controlled drugs, and listed  
4       chemicals from the effective date of the agreement to the  
5       date of the compliance review by the particular distribution  
6       center being reviewed."

7           Did I read that correctly?

8       **A.**   Yes.

9       **Q.**   Would you expect the DEA to ask where they thought it  
10      was appropriate for -- and let's underline "sales of  
11      controlled substances, non-controlled drugs, and listed  
12      chemicals."

13      **A.**   Yes.

14      **Q.**   And then it says at the conclusion of each compliance  
15      review, DEA shall conduct an exit interview with an  
16      appropriate McKesson representative to provide DEA's  
17      preliminary conclusions regarding the compliance review.

18           Do you see that reference to the exit interview?

19      **A.**   Yes, I do.

20      **Q.**   Do you know -- would you expect those exit interviews  
21      to have occurred given this obligation in this Settlement  
22      Agreement?

23      **A.**   Yes.

24      **Q.**   Do you know of any concerns raised in those exit  
25      interviews with McKesson on any of these points, the

1 functionality of its diversion compliance program, the  
2 investigatory files maintained, or any information requested  
3 in these other categories?

4 **A.** No, I do not know personally.

5 **Q.** Let's look at Subsection (f), please. That's the next  
6 section in the 2008 Settlement Agreement, Page 6 of Defense  
7 West Virginia -- I'm sorry -- P-23733.

8 You were shown this sentence at the end that says, "A  
9 finding of satisfactory does not otherwise express DEA's  
10 approval of the compliance program implemented at any  
11 particular distribution center."

12 Do you remember being shown that language yesterday?

13 **A.** Yes.

14 **Q.** Do you see where it says "does not otherwise express  
15 approval"?

16 **A.** Yes.

17 **Q.** So let's look at what is being reviewed.

18 The first sentence says, "The compliance reviews will  
19 be deemed satisfactory unless DEA determines that one or  
20 more of the facilities being inspected has, one, failed to  
21 maintain effective controls against diversion regarding the  
22 distribution of any controlled substance."

23 Do you see that?

24 **A.** Yes.

25 **Q.** "Two, failed to detect and report to DEA suspicious

1 orders of controlled substances."

2 Do you see that?

3 **A.** Yes.

4 **Q.** Or, "Three, failed to meaningfully investigate new or  
5 existing customers regarding the customer's legitimate need  
6 to order or purchase controlled substances."

7 Do you see that?

8 **A.** Yes.

9 **Q.** Would you expect the DEA to carry out its  
10 responsibilities to only deem these compliance reviews  
11 satisfactory unless there's a finding of failure to maintain  
12 effective controls, failure to detect and report suspicious  
13 orders, or failure to meaningfully investigate new or  
14 existing customers?

15 **A.** Yes, during that, during that snapshot period of  
16 review, yes.

17 **Q.** And you know McKesson passed those compliance reviews;  
18 correct?

19 **A.** Yes, during that snapshot period of review, yes.

20 **Q.** And you know of no concerns that the DEA raised on any  
21 of these specific factors that they were reviewing in order  
22 to deem the distribution center satisfactory?

23 **A.** Again, during that, that short time period of review,  
24 yes, they did not find anything.

25 **Q.** I want to come back to a point we talked about before

1       the break. Did I hear you correctly that although it  
2       doesn't appear in the regulation, you said in your  
3       distributor letters that they were supposed to identify for  
4       a suspicious order what the issue is with the pharmacy? Did  
5       I understand that correctly? Remember I said I'll come back  
6       to that?

7       **A.**     Yeah. I -- they were supposed to explain what created  
8       the suspicious nature of the order which is basically due  
9       diligence.

10      **Q.**     Were they -- sorry.

11      **A.**     A suspicious order is not just, oh, it's over the  
12       threshold. It could be over threshold because it's next to  
13       a cancer center or palliative care center, a hospital.  
14       There's got to be something just -- threshold, that's  
15       exactly what due diligence is. It's looking at a suspicious  
16       order above threshold. There's got to be some reason it's  
17       above threshold. And that's got to be explained, yes.

18      **Q.**     Did you testify before the break that you told  
19       distributors in your letters that they had to identify what  
20       the issue with the pharmacy was when they reported a  
21       suspicious order to that pharmacy? Did you give that  
22       testimony?

23      **A.**     Yes, I believe I said the letters and/or -- I think it  
24       was the letters or the distributor initiative briefings, but  
25       I think I said letters, yes.

1       **Q.**    I think you did too. So let's take a look at those  
2 letters. Do you have in front of you P-32, sir? This is  
3 the packet that contains the letters.

4       **A.**    Yes.

5       **Q.**    Okay. And go to Page 9. Do you see your  
6 September 27th, 2006, letter?

7       **A.**    I don't think it's in the 2006 letter.

8       **Q.**    Okay. If you don't think it's there, let's go to the  
9 December one. If you go to Page 3, do you see your  
10 December 27th, 2007, letter?

11      **A.**    Yes.

12      **Q.**    Let's go to the second page, please, and if we can cull  
13 out the second paragraph.

14           It states, "When reporting an order as suspicious,  
15 registrants must be clear in their communications with DEA  
16 that the registrant is actually characterizing an order as  
17 suspicious."

18           Do you see that?

19      **A.**    Yes.

20      **Q.**    That's that idea you have to tell us you think it's  
21 suspicious under your criteria; correct?

22      **A.**    Yes.

23      **Q.**    Is there anywhere in this letter where you tell them  
24 you have to explain what it is about the pharmacy that makes  
25 it suspicious?

1       **A.**     That's due diligence. So, naturally, just over  
2 threshold tells us nothing. It needs to be more than that.  
3 No, in that letter, no, there's nothing. But we've  
4 explained to them -- we explained to them in the distributor  
5 initiative briefings what due diligence is.

6       **Q.**     I'm not asking about due diligence, sir. I'm asking  
7 about reporting suspicious orders. You did not attend the  
8 due diligence briefings with McKesson, ABDC, or Cardinal;  
9 correct?

10      **A.**     That's correct.

11      **Q.**     And in your letter, your letters, you do not tell  
12 McKesson, ABDC, or Cardinal that they need to, when they  
13 report suspicious orders, explain what it is about the  
14 pharmacy that is triggering the report; correct?

15      **A.**     Well, a suspicious order is specific on the pharmacy.  
16 So it's not in that letter. However, --

17      **Q.**     It's not in any of your letters, is it, sir?

18      **A.**     No. Now that I -- I know it's not in the '6 one so --

19      **Q.**     Okay. Let's, let's switch gears. I want to talk about  
20 the closed system. Do you remember giving testimony that  
21 was one of the stops, or several of the stops on the road  
22 map, the closed system?

23      **A.**     Yes.

24      **Q.**     Let's go back to those stops on the road map. And I  
25 want to start with the mission of the Office of Diversion

1 Control. And I'll give you a document I've marked as  
2 Defense West Virginia 2408.

3 MR. SCHMIDT: May I approach, Your Honor?

4 THE COURT: Yes.

5 THE WITNESS: Thank you.

6 MR. SCHMIDT: Thank you.

7 BY MR. SCHMIDT:

8 Q. Do you have that in front of you, Defense West  
9 Virginia 2408?

10 A. Yes.

11 Q. Do you recognize it as a printout from the Diversion  
12 Control division at DEA that talks about their mission?

13 A. Yes.

14 MR. SCHMIDT: We move this into evidence, Your  
15 Honor.

16 THE COURT: Any objection?

17 MR. ACKERMAN: The objection is foundation, Your  
18 Honor. I don't know that -- it talks about the -- it's not  
19 related to a time period where he was at DEA.

20 BY MR. SCHMIDT:

21 Q. Do you recognize this --

22 MR. SCHMIDT: I'll take care of that, Your Honor,  
23 if I could.

24 BY MR. SCHMIDT:

25 Q. Look with me under "About Us." Do you see that?

1           **A.**     Yes.

2           **Q.**     Just read to yourself the mission of DEA. Do you see  
3     that? Tell me when you've had a chance to read that.

4                         (Pause)

5           **A.**     Yes.

6           **Q.**     Do you recognize that as the mission of the Office of  
7     Diversion Control when you were at DEA?

8           **A.**     Yes. That's a mission statement we used.

9                         MR. SCHMIDT: I move it into evidence on that  
10   basis, Your Honor.

11                         MR. ACKERMAN: No objection.

12                         THE COURT: It's admitted.

13                         BY MR. SCHMIDT:

14           **Q.**     So I want to break down that mission a little bit  
15     and I want to start -- well, let me ask, do you  
16     recognize this? It's a two-part mission, correct,  
17     according to this mission statement?

18           **A.**     Yes.

19           **Q.**     I want to talk about both parts of that mission if I  
20     could. Let me see if I can switch to the white board if  
21     that's okay.

22                         Do you still have that language in front of you, Mr.  
23     Rannazzisi? I'm just going to write part of it up on the  
24     screen if that's okay.

25                         MR. SCHMIDT: Am I okay erasing this?

1 MS. SINGER: I think it's been saved. Excuse me.

2 I think it's been saved.

3 MR. SCHMIDT: Okay.

4 MR. ACKERMAN: Your Honor, I'm going to move over  
5 there so I can see the board.

6 THE COURT: You may.

7 BY MR. SCHMIDT:

8 **Q.** All right. So looking with me at Exhibit 2408, is  
9 part of the mission of the Office of Diversion Control  
10 to prevent, detect, and investigate the diversion of  
11 controlled pharmaceuticals and listed chemicals? Is  
12 that one of the missions of Office of Diversion Control?

13 **A.** Yes, it is.

14 **Q.** I'm going to shorthand it by writing "prevent  
15 diversion." And then it continues on and says, "while  
16 ensuring an adequate and uninterrupted supply for legitimate  
17 medical, commercial, and scientific needs."

18 Do you recognize that as the other mission of the  
19 Office of Diversion Control?

20 **A.** Yes.

21 **Q.** Let me -- "while ensuring an adequate and uninterrupted  
22 supply." And let me ask you about both halves of this  
23 starting with preventing diversion.

24 In preventing diversion and in carrying out that  
25 mission, the DEA is charged with protecting the public from

1 the harms of diversion; correct?

2 **A.** That is correct.

3 **Q.** In fact, one of the DEA's core functions is to prevent  
4 the diversion of controlled substances into illicit  
5 channels; correct? That's a core function of the DEA?

6 **A.** Yes.

7 **Q.** At the same time, and I think you talked about this in  
8 some of your testimony yesterday particularly on quota, DEA  
9 has a mission to ensure an adequate and uninterrupted supply  
10 of controlled substances; correct?

11 **A.** That's correct.

12 **Q.** And you agree that it's vital that an adequate and  
13 uninterrupted supply of pharmaceutical controlled substances  
14 be available for effective patient care?

15 **A.** Yes.

16 **Q.** It's a public health concern when pharmacies cannot  
17 dispense legitimate pharmaceutical controlled substances to  
18 patients; correct?

19 **A.** To legitimate patients, yes.

20 **Q.** There can be no doubt that drug shortages adversely  
21 affect the public health; correct?

22 **A.** That's, that's obvious, yes.

23 **Q.** All right. From your experience, you agree that when  
24 it comes to the supply of prescription opioids, supply does  
25 not drive demand?

1           **A.** Supply does not drive demand.

2                   MR. ACKERMAN: Your Honor, while Mr. Schmidt is  
3 writing, if it's at all possible for the Court to move that  
4 to our screens, then I don't need to stand here with my  
5 friends.

6                   MR. SCHMIDT: Yeah, no objection, of course.

7                   THE COURT: Yeah. Just find a good place there,  
8 Mr. Ackerman.

9                   MR. SCHMIDT: I'm sorry. Before you switch it,  
10 the problem is that we may need to put up documents on the  
11 individual screen.

12                  MR. ACKERMAN: All right. I'll find a chair over  
13 here.

14                  MR. SCHMIDT: There's an empty one at my table.

15                  (Laughter)

16 BY MR. SCHMIDT:

17           **Q.** Going back to this point, when it comes to demand  
18 for prescription opioids, that comes not from supply but  
19 from prescribing and dispensing in hospitals; correct?

20           **A.** No, not necessarily. Demand also -- when we're talking  
21 about quota, it has things to do with research and  
22 development, validation, export, things like that.

23           **Q.** When it comes to -- let me rephrase. When it comes to  
24 demand, demand comes from things like prescribing,  
25 hospitals, research and development, export; correct?

1       **A.**   For that portion of the quota. Well, yeah, total, yes.

2 Q. The demand is driven by patient care and patient needs;  
3 correct?

**A.** A large part of the quota is patient needs.

5 Q. Not by supply; correct? I didn't hear if you answered.  
6 I apologize, sir. Not by supply; correct?

**A.** No, supply is not what drives demand.

8 COURT REPORTER: I'm sorry?

9 THE WITNESS: Demand drives the quota.

10 BY MR. SCHMIDT:

11 Q. Your understanding of what drives demand for  
12 opioids is appropriate medical treatment; correct?

**A.** Yes, if -- appropriate medical treatment, yes.

14 Q. And prescription opioid levels in turn -- prescription  
15 opioid levels in turn are based on the presumption that  
16 medical need is legitimate; correct?

17       **A.**     Yes. Appropriate medical treatment does drive some of  
18           the demand, yes.

19 Q. And just because you have a supply of prescription  
20 opioids does not mean the supply must be used; correct?

21           **A.**     That's correct.

22 Q. Correspondingly, reducing supply doesn't necessarily  
23 reduce demand; correct?

**A.** That's correct.

25 Q. All right. Now, in terms of supply level, you never

1 provided guidance at DEA to tell companies that for a given  
2 dose or type of prescription opioid if they see doses above  
3 that level, they should investigate, did you?

4 **A.** I personally didn't.

5 **Q.** Okay.

6 MR. SCHMIDT: May I approach, Your Honor?

7 THE COURT: Yes.

8 BY MR. SCHMIDT:

9 **Q.** I've passed you a document marked P-23594-001. Do  
10 you know what this document is?

11 **A.** Yes. I believe these are the summary reports that we  
12 put on the DEA website.

13 MR. SCHMIDT: I move this into evidence, Your  
14 Honor.

15 THE COURT: Yes.

16 MR. ACKERMAN: No objection.

17 THE COURT: Did you move its admission?

18 MR. SCHMIDT: I did, Your Honor.

19 THE COURT: And there's no objection; right?

20 MR. ACKERMAN: No objection.

21 THE COURT: I was reading it and I wasn't paying  
22 attention. It's admitted.

23 BY MR. SCHMIDT:

24 **Q.** All right. If we look at the cover of this  
25 document, do you see it says "Department of Justice"?

1       And it's on your screen as well, just not on the big  
2       screen.

3       **A.**     Yes.

4       **Q.**     And it says "ARCOS Report 4." Do you see that?

5       **A.**     Yes.

6       **Q.**     And it says reporting period January, 2010 to December,  
7       2010. Do you see that?

8       **A.**     Yes.

9       **Q.**     And this is, this is that portion of the ARCOS data the  
10      DEA reported to the public; correct?

11      **A.**     Yes.

12      **Q.**     And I've chosen this period of time because there's  
13      been a focus on this period of time in terms of a high  
14      level, or purportedly high level of prescription opioids  
15      during this time period.

16           So let's -- having said that, let's look at Page 21 of  
17      this report. Actually, let's start with Page 18. I  
18      apologize.

19           And if we look at -- tell me when you're there, sir.

20      **A.**     I believe I'm there.

21      **Q.**     Okay. If you look at the left-hand side about  
22      two-thirds of the way down, and if you can pull it up a tiny  
23      bit, just pull up the screen a tiny bit. There we go.

24           It says U.S. grams per hundred thousand, Drug Code  
25      9143, drug name hydrocodone [sic].

1           Do you see that?

2       **A.**   Yes.

3       **Q.**   Do you have an understanding that this is the DEA  
4           reporting the average grams per hundred thousand people for  
5           different states for oxycodone?

6       **A.**   Based on ARCOS, yes.

7       **Q.**   Correct?

8       **A.**   It's the amount of drugs that ARCOS, on an ARCOS  
9           analysis has gone into these states per 100,000.

10      **Q.**   And if we look at West Virginia, West Virginia is 9.  
11      Do you see that?

12      **A.**   Yes.

13      **Q.**   Let's go to 21. And, very quickly, do you see that 21  
14           reports the same data for hydrocodone? This time West  
15           Virginia at this point in time is number 7. Do you see  
16           that?

17      **A.**   Yes.

18      **Q.**   When you were at DEA, did you ever issue guidance to  
19           distributors, the healthcare community, doctors that these  
20           levels were too high?

21      **A.**   No, I did not.

22      **Q.**   Are you aware that the DEA also publishes this data at  
23           the zip code level?

24      **A.**   I'm sorry?

25      **Q.**   At the zip code level.

1           **A.**     Yes, uh-huh.

2                   MR. SCHMIDT: May I approach?

3                   THE COURT: Yes. You should have bought stock in  
4 International Paper, Mr. Schmidt.

5                   MR. ACKERMAN: At some point, Your Honor, I'm sure  
6 someone is going to object on behalf of the earth.

7                   MR. SCHMIDT: Someone should. I'm happy to do  
8 less.

9                   BY MR. SCHMIDT:

10                  **Q.**    This is a lot of paper for a little point.

11                  Do you see that this is 23591 and it's a similar retail  
12 drug summary report, but this time by zip code within the  
13 state? Do you see that?

14                  **A.**     Yes.

15                  MR. SCHMIDT: We move this into evidence, Your  
16 Honor.

17                  THE COURT: Any objection?

18                  MR. ACKERMAN: No objection.

19                  THE COURT: It's admitted.

20                  BY MR. SCHMIDT:

21                  **Q.**     Let's look at Page 354, please. Do you see that on  
22 Page 354 -- I thought it said oxycodone on this page.  
23 I'll represent to you that this is the oxycodone levels.  
24 You can flip back in the report to confirm that.

25                  Do you see the report of the oxycodone levels by zip

1 code on Page 354?

2 **A.** Yes.

3 **Q.** And if we look at zip codes 255 and 257, do you see  
4 those zip codes?

5 **A.** Yes.

6 **Q.** And I'll represent to you that those zip codes include  
7 Huntington and Cabell County, but they also include  
8 additional areas. Is that something you were aware of?

9 **A.** No.

10 **Q.** Did DEA ever issue any guidance in connection with  
11 issuing a report like this at any point in time to  
12 healthcare providers, manufacturers, distributors,  
13 pharmacies that specific levels at the zip code level were  
14 too high?

15 **A.** No. DEA would not issue something like that.

16 **Q.** Did they ever say certain levels merited investigation?

17 **A.** No. The reason this is put on there is to help  
18 healthcare providers, public health officials, law  
19 enforcement, different organizations knowing what's going  
20 into their systems. That's why it's on the DEA website.

21 **Q.** That was the intent, to let entities like the City of  
22 Huntington and Cabell County know exactly what was going  
23 into their communities?

24 **A.** Health departments, state health departments, things  
25 like that. We wanted to get it out there about exactly

1 population wise how much drug is going into the areas.

2 **Q.** So that they could act as appropriate if they deemed it  
3 appropriate?

4 **A.** The information was presented for their -- whatever  
5 they deemed appropriate.

6 **Q.** Okay. I want to talk about some of the participants  
7 now in the closed system that you touched on with the Court  
8 yesterday and the day before.

9 Anyone who handles a controlled substance has to be  
10 registered with the DEA; correct?

11 **A.** Except for nurses and pharmacists.

12 **Q.** Nurses have to operate under the direction of doctors;  
13 correct?

14 **A.** Or hospitals.

15 **Q.** Or hospitals. And pharmacists have to be affiliated  
16 with a pharmacy that's registered; is that correct?

17 **A.** Yes, uh-huh.

18 **Q.** And that DEA registration includes prescribers; right?

19 **A.** Yes.

20 **Q.** Prescribers can only write prescriptions for  
21 prescription opioids if they're licensed with their state  
22 but also if they're registered with the DEA; correct?

23 **A.** Yes.

24 **Q.** Did you have an understanding when you were at the DEA  
25 as to why there's a separate requirement for DEA

1 registration in addition to the requirement that they be  
2 licensed by the state?

3 **A.** So a DEA registration authorizes them to have a -- to  
4 handle controlled substances. The state registration,  
5 because they're licensed to practice medicine or whatever  
6 they're practicing, and also there's a separate state  
7 license for controlled substances but -- in some states.

8 So there's -- it's a two-part system. You've got to be  
9 registered by the state. The state has to grant you a  
10 license. And then DEA will come and grant you their  
11 license.

12 **Q.** My question was a little different, sir. My question  
13 was why is there a DEA requirement of a separate DEA  
14 registration in order to prescribe controlled substances, if  
15 you know? Why not just have the state requirement?

16 **A.** Because under the Controlled Substances Act it's  
17 required.

18 **Q.** Do you know why?

19 **A.** Yeah, because the federal government wants to ensure  
20 that controlled substances under the Act are being handled  
21 appropriately.

22 **Q.** You understand that registration had to be renewed  
23 every three years?

24 **A.** Yes.

25 **Q.** And just so -- actually, I'll skip moving in the

1 regulation.

2 Did you have an understanding when you were at DEA as  
3 to why prescribers weren't simply given a lifetime  
4 registration from DEA, why they had to be renewed every  
5 three years?

6 **A.** To ensure that they're appropriately licensed and that  
7 they did not have anything in their backgrounds during that  
8 three-year period that could warrant them, you know,  
9 disqualifying them from getting a license, a DEA  
10 registration.

11 **Q.** I'm going to show you P-4215 if I could. I just  
12 misread it. I apologize. It's P-42145.

13 MR. SCHMIDT: May I approach, Your Honor?

14 BY MR. SCHMIDT:

15 **Q.** Mr. Rannazzisi, do you recognize this as a DEA  
16 regulation regarding prescriptions for controlled  
17 substances?

18 **A.** Yes.

19 MR. SCHMIDT: We move this into evidence, Your  
20 Honor.

21 THE COURT: Any objection?

22 MR. SCHMIDT: P, Plaintiffs' 42145.

23 MR. ACKERMAN: No objection.

24 THE COURT: It's admitted.

25 BY MR. SCHMIDT:

1       **Q.**    In this regulation in the second sentence it  
2        states, "The responsibility for the proper prescribing  
3        and dispensing of controlled substances is upon the  
4        prescribing practitioner."

5                  Do you see that language?

6       **A.**    Yes.

7       **Q.**    And then it refers to a corresponding responsibility  
8        with the pharmacist who fills the prescription; correct?

9       **A.**    That's correct.

10      **Q.**    And only a DEA registered practitioner may make the  
11       determination if a controlled substance is medically  
12       necessary; correct?

13      **A.**    For a particular patient.

14      **Q.**    Yes.

15      **A.**    For prescribing, yes.

16      **Q.**    And a distributor cannot make the determination if a  
17       controlled substance is medically necessary for a particular  
18       patient; correct?

19      **A.**    Yes. And we've never asked a distributor to do that.

20      **Q.**    Fair. In fact, yesterday you testified that you were  
21       not asking distributors to become doctors and figure out  
22       what's legitimate and what's not; correct?

23      **A.**    That's correct.

24      **Q.**    Yesterday you testified that you never required  
25       distributors to look at what doctors were doing, questioning

1 a doctor's prescribing habits; correct?

2 **A.** That's correct.

3 **Q.** Why are DEA registered practitioners the only ones who  
4 can make the determination that a medication is appropriate  
5 for an individual patient?

6 **A.** Because they have to make a determination that the  
7 medication that they're prescribing meets the needs, medical  
8 needs of that particular patient. They're seeing that  
9 patient. No one else is.

10 **Q.** Okay. Was there ever an occasion you know of where you  
11 or someone at DEA told one of the distributors in this case  
12 that they should stop supplying to a pharmacy in Huntington  
13 or Cabell because of a DEA registered doctor whose  
14 prescriptions were being filled at that pharmacy?

15 **A.** I've never done that, and I don't know of anybody among  
16 the staff that has when I was there.

17 **Q.** You would agree with me that -- and I think you talked  
18 about some of these statistics yesterday. I just want to  
19 make sure we're on the same page.

20 During your time at DEA, 99.5 percent of prescribers  
21 were not over-prescribing; correct?

22 **A.** Yeah, we used that number. We generally used  
23 99 percent but we've gone to .5.

24 **Q.** And I don't want to quibble, but because I've written  
25 99.5 on the board, do you want to see your congressional

1           testimony where you said that?

2       **A.**    That's fine.

3       **Q.**    You don't take issue with it; right?

4       **A.**    We've used 99 percent too. It just depends on when  
5       we're talking.

6       **Q.**    Yeah, understood. And that's what I want to go to  
7       next. You've actually said 99 percent of doctors are  
8       perfect. Correct?

9       **A.**    Yeah, I've said that they're doing things  
10      appropriately, yes.

11      **Q.**    That they're perfect; correct?

12      **A.**    I don't recall saying "perfect," but I may have during  
13      one presentation.

14                  MS. SINGER: Objection, Your Honor. I don't think  
15      what Mr. Schmidt wrote is what Mr. Rannazzisi just  
16      testified.

17                  MR. SCHMIDT: Let me see if I can cure that, Your  
18      Honor.

19      BY MR. SCHMIDT:

20      **Q.**    Defense West Virginia 620. Do you remember being  
21      asked about giving congressional testimony at various  
22      points in time, Mr. Rannazzisi?

23                  MR. SCHMIDT: May I approach, Your Honor?

24                  THE COURT: Yes.

25                  THE WITNESS: Yes.

1                   MR. SCHMIDT: If there's no objection, we'll start  
2 doing excerpts on these bigger documents. It does seem a  
3 waste to do all this for a small part at this point.

4 BY MR. SCHMIDT:

5 **Q.** If we look at Defense West Virginia 620, it's a  
6 hearing before a House of Representatives Committee,  
7 March 1st, 2012. Do you see that?

8 **A.** Yes.

9 **Q.** And then if we go to -- I'm using the numbers in the  
10 lower left corner, Page 98. You'll see various comments  
11 from you, including a larger one in the top half, right  
12 barely above the top half of the page. Do you see that?

13 **A.** On page -- which page?

14 **Q.** Page 98 in the lower left-hand corner.

15 **A.** Yes, I've got it.

16 **Q.** And if you look at the second sentence there that  
17 begins "the problem," do you see that? Do you see where you  
18 say, "The problem is that the doctors continue," and then  
19 you stop, "not all doctors, 99 percent of the doctors are  
20 perfect."

21                   Do you see that you said that before Congress?

22 **A.** Maybe I'm not on the right page then. What's the page  
23 on top?

24 **Q.** The page on top is 94.

25 **A.** Okay. I'm there.

1       **Q.**   And it's the third quote from you on the page right  
2 before the halfway mark.

3       **A.**   Okay. I see it. I see it.

4       **Q.**   Do you see where you said to Congress 99 percent of the  
5 doctors are perfect? Do you see that?

6       **A.**   Yes.

7       **Q.**   Were you trying to be accurate and correct in your  
8 testimony to Congress?

9       **A.**   I was giving an estimate on what DEA has said in the  
10 past.

11      **Q.**   Okay.

12                   THE COURT: Do you still object, Ms. Singer?

13                   MS. SINGER: I don't think it's worth the  
14 objection, Your Honor, so I withdraw the objection.

15                   MR. SCHMIDT: Thank you.

16                   BY MR. SCHMIDT:

17       **Q.**   You repeatedly stated, including to Congress  
18 throughout your tenure, that the overwhelming majority  
19 of prescribing in America is conducted responsibly.  
20 Correct?

21       **A.**   Yes.

22       **Q.**   And during your tenure, you also said that the DEA  
23 recognizes that nearly every prescription issued by a  
24 physician in the United States is for a legitimate medical  
25 purpose in the usual course of professional practice;

1                   correct?

2                   **A.**     Where, where did I say that? I've got to go back and  
3                   look at that.

4                   **Q.**     Okay. Let's take a look at that.

5                   MR. SCHMIDT: May I approach, Your Honor?

6                   THE COURT: Yes.

7                   BY MR. SCHMIDT:

8                   **Q.**     This is a statement from the Federal Register  
9                   DEA -- while you were at DEA. Do you see that?  
10                  September 6th, 2006?

11                  **A.**     Yes.

12                  **Q.**     Okay.

13                  MR. SCHMIDT: We move this into evidence, Your  
14                  Honor, Defense West Virginia 3076.

15                  THE COURT: Any objection to this one?

16                  MR. SCHMIDT: Actually, this is in evidence.  
17                  Nevermind.

18                  THE COURT: Oh, it's in evidence.

19                  MR. SCHMIDT: I'm sorry.

20                  BY MR. SCHMIDT:

21                  **Q.**     Let's go to the second page.

22                  **A.**     Uh-huh.

23                  **Q.**     On the second page in the upper left corner it says,  
24                  "Drug Enforcement Administration." And it says "Action:  
25                  Policy Statement." Do you see that this is a policy

1 statement of the DEA while you were there?

2 **A.** Yes, sir. I was -- yes, sir.

3 **Q.** It's a policy statement regarding, quote, dispensing  
4 controlled substances for the treatment of pain. Do you see  
5 that?

6 **A.** Yes.

7 **Q.** And it's a policy statement, if we look for further  
8 information -- if we look -- strike that. If we look a  
9 little further down, it says, "For further information,  
10 contact." Do you see that?

11 **A.** Yes.

12 **Q.** And it has someone in the Office of Diversion Control,  
13 the office you oversaw. Do you see that?

14 **A.** Yes.

15 **Q.** And did you supervise this person, Mr. Caverly?

16 **A.** Yes.

17 **Q.** Were you responsible for this policy statement when it  
18 came out?

19 **A.** We were a part of drafting of this policy statement,  
20 yes.

21 **Q.** Okay. So let's look at this policy statement. This is  
22 one of those documents that we talked about yesterday with  
23 Ms. Singer that were issued to give guidance to doctors and  
24 others. Right?

25 **A.** I've got to re-read this policy statement. I -- it's a

1 policy statement regarding the treatment of pain, if I'm not  
2 mistaken.

3 **Q.** Okay.

4 **A.** But I have to go back and read it. If this is the same  
5 one I'm thinking about, it's very detailed and there's a lot  
6 of information. So I would have to go back and read this.

7 But --

8 **Q.** Okay.

9 **A.** So let me just -- with that caveat.

10 **Q.** Okay. Let me see if I can help you. Let's go to the  
11 second page on the right-hand column. And it says -- you've  
12 got it on the screen.

13 It says "Purposes and structure of this document." Do  
14 you see that?

15 **A.** Yes.

16 **Q.** And this document came from the Office of Diversion  
17 Control; correct?

18 **A.** It -- well, it came from the administrator. The  
19 administrator signed the document.

20 **Q.** You had a role in this document; correct?

21 **A.** I was at the Office of Diversion Control during this  
22 time period.

23 **Q.** Did you have a role in this document?

24 **A.** I, I reviewed the document, yes.

25 **Q.** One of the chief purposes of the document is to make

1 clear that the long-standing requirement under the law that  
2 physicians may prescribe controlled substances only for  
3 legitimate medical purposes in the usual course of  
4 professional practice should in no way interfere with the  
5 legitimate practice of medicine or cause any physician to be  
6 reluctant to provide legitimate pain treatment.

7 Do you see that?

8 **A.** Yes.

9 **Q.** This was giving guidance to doctors; right?

10 **A.** Yes.

11 **Q.** All right. And then if we go to Page 7, please, in the  
12 lower left corner, and tell me when you're there.

13 **A.** Okay.

14 **Q.** And I'm going to direct your attention to the  
15 right-hand column right before the bolded heading which we  
16 have up on the screen. And it has that language I started  
17 off by reading.

18 "To the contrary, the agency recognizes that nearly  
19 every prescription issued by a physician in the United  
20 States is for a legitimate medical purpose in the usual  
21 course of professional practice."

22 Was that stated in the policy statement from the DEA  
23 when you were at the DEA running the Office of Diversion  
24 Control?

25 **A.** Yeah. I don't remember that statement but, again, I

1 know this document was not just -- it was published as a DEA  
2 document, but there were other, other agencies and  
3 government agencies and entities involved in this document.

4 **Q.** Okay. But you see where it says nearly every  
5 prescription -- and I'm going to write Rx for short -- is  
6 for a legitimate medical purpose. Do you see that?

7 **A.** Yes.

8 **Q.** Do you take issue with this as a true statement, sir?

9 **A.** From -- I would say, I would say the vast majority of  
10 the prescriptions. I wouldn't say nearly every. Nearly  
11 every is pretty, pretty focused. I don't think that's the  
12 case.

13 **Q.** Did you ever take any steps to repudiate this statement  
14 in an official DEA policy statement on your watch?

15 **A.** Again, it's official policy statement that was made by  
16 not only DEA but the department and other entities within  
17 the United States government. It just was a vehicle. The  
18 DEA Federal Register was the vehicle to get that out.

19 **Q.** Do you mind answering my question now, sir?

20 **A.** Which is?

21 **Q.** Did you take any steps to repudiate that statement  
22 while you were at DEA?

23 **A.** I don't recall taking any steps to retract or repudiate  
24 the statement.

25 **Q.** Okay. In the same document you talked about the idea

1       of doctors acting improperly, and I want to direct your  
2       attention to that.

3           Could we go to Page 5 of this document. And tell me  
4       when you're there.

5           Let's cull up the right-hand column, just the heading.

6 **A.**    Okay. I'm on Page 5.

7 **Q.**    Can we cull up Page 5, Defense West Virginia 3076, so  
8       we're all looking at the same thing. Is it available to put  
9       up on the screen? Thank you.

10          And while we do, let me read the title in the record,  
11       the heading -- I'm sorry -- of this subsection.

12          It says, "The number of physicians who prescribe  
13       controlled substances in violation of the CSA --" and now we  
14       see it on the screen -- "is extremely small and there is no  
15       DEA crackdown on physicians."

16          Do you see that in this policy statement that when it  
17       comes to the physicians who prescribe controlled substances  
18       in violation of the CSA, that is extremely small? Do you  
19       see that?

20 **A.**    Yes, as compared to the patient population, yes, the  
21       physician population, prescriber population, yes.

22 **Q.**    That's a true statement; right?

23 **A.**    Yes.

24 **Q.**    And it then goes on to characterize that. It has that  
25       "overwhelming majority" language you and I have talked

1       about. DEA recognizes that the overwhelming majority of  
2       American physicians who prescribe controlled substances do  
3       so for legitimate medical purposes.

4                  Do you see that?

5       **A.** Yes.

6       **Q.** In fact, the overwhelming majority of physicians who  
7       prescribe controlled substances do so in a legitimate manner  
8       that will never warrant scrutiny by federal or state law  
9       enforcement officials. Do you see that?

10      **A.** Yes.

11      **Q.** And is that a true statement?

12      **A.** Yes.

13      **Q.** And then you quantify actions against doctors in the  
14       italicized sentence, if we can scroll down in this column,  
15       please.

16                  Do you see a little further down there's an italicized  
17       sentence? Do you see that?

18      **A.** Yes.

19      **Q.** "In any given year, including 2005, fewer than one out  
20       of every 10,000 physicians in the United States (less than  
21       .01 percent) lose their controlled substance registrations  
22       based on a DEA investigation of improper prescribing."

23                  Did I read that correctly?

24      **A.** Yes.

25      **Q.** Is that accurate that in a given year less than

1 .01 percent of physicians in the United States lose their  
2 controlled substance registration based on a DEA  
3 investigation of improper prescribing?

4 **A.** Back in 2005 and prior to, yes.

5 **Q.** Was that true in 2007 when you gave the same testimony  
6 before Congress?

7 **A.** I'm not sure in 2007 if that's true or not. I would, I  
8 would guess that the numbers -- I just don't recall. But,  
9 but this is specific to prior to 2005. So if there's some  
10 other document or -- I've looked at it, but I just don't  
11 recall saying that except for 99 percent of the prescribers.  
12 Generally, 99 percent of the prescribers are doing exactly  
13 what they're told to do.

14 MR. SCHMIDT: May I approach, Your Honor?

15 THE COURT: Yes.

16 MR. SCHMIDT: Actually, can we just put it up on  
17 the screen because it's impeachment? We have it here.

18 THE WITNESS: Thank you.

19 MR. SCHMIDT: You're welcome.

20 BY MR. SCHMIDT:

21 **Q.** I've passed you MC-WV-2172, testimony before House  
22 of Representatives Subcommittee on July 12th, 2007. Do  
23 you see that?

24 **A.** Yes.

25 **Q.** If you go to Page 11 in the bottom left-hand corner

1       you'll see a prepared statement from you read into the  
2 record. Do you see that?

3       **A.** Yes.

4       **Q.** And if you go to Page 12, the fifth full paragraph,  
5 generally speaking, do you see you again in July of 2007  
6 saying, "In any given year DEA arrests less than .01 percent  
7 of the 750,000 doctors registered with the DEA for a  
8 criminal violation." Do you see that?

9       **A.** Yes. That's specific to a criminal violation.

10      **Q.** Okay.

11      **A.** That's what it says, a criminal violation.

12      **Q.** Okay.

13      **A.** It doesn't say anything about administrative actions.

14      **Q.** I'm not going to ask you about those further. Do you  
15 want me to take back any of those large documents?

16      **A.** I would love for you to take back some of these large  
17 document.

18      **Q.** That's the only time you'll ever say that to me. But  
19 the testimony, if you want to give me that, all the  
20 suspicious order reports, if you want to give me those.

21      **A.** Yes.

22      **Q.** All right. So if we go back to this 2006 policy  
23 statement from DEA, Defendants' West Virginia 3076, I want  
24 to go back to Page 5, please. And let's look at that  
25 italicized sentence we were highlighting.

1           Have you ever publicly identified what percentage of  
2 opioid prescriptions in a given year are written by this  
3 .01 percent versus the remaining 99.9 percent? Is that  
4 something you've ever quantified for the public?

5       **A.**   No.

6       **Q.**    Do you know if any of the doctors in Huntington or  
7 Cabell on your watch were in this .01 percent?

8       **A.**    I do not know.

9       **Q.**    And when you identified those .01 percent who lost  
10 their registrations on the other example were criminally  
11 prosecuted, did you make that determination just by looking  
12 at their prescribing levels or did you require more  
13 information?

14      **A.**    Oh, it would require an investigation, a full  
15 investigation.

16      **Q.**    Did you ever have a criteria that if a doctor fell  
17 within the top one percent, they would automatically be  
18 investigated in terms of their prescribing levels?

19      **A.**    Doctors are investigated based on a specific set of  
20 facts. And after that, you know, we get into an  
21 investigative process.

22      **Q.**    My question was simply was there ever --

23      **A.**    I'm sorry. I said doctors investigated by specific --  
24 it's fact-based, specific set of facts. So we don't  
25 investigate based on quantities.

1       **Q.**    You answered my question. Thank you. You looked at a  
2 range of factors to determine --

3       **A.**    A range of factors, yes.

4       **Q.**    A range of factors beyond simply quantity; correct?

5       **A.**    Yes, for doctors, yes.

6       **Q.**    Yes. Now, the DEA made these statements about  
7 prosecutions being rare in the context of wanting to  
8 encourage doctors that they could prescribe prescription  
9 opioids as medically appropriate without being concerned  
10 about the DEA cracking down on them; correct?

11      **A.**    We wanted to assure doctors that if they were  
12 prescribing appropriately, they would never have problems  
13 with DEA as long as they were prescribing for legitimate  
14 medical purpose in the usual course of professional  
15 practice.

16      **Q.**    In fact, if we look at -- if we look at the document we  
17 were just looking at 3076-5, the policy statement, the  
18 language we were just looking at, the heading, Page 5, that  
19 heading says there is no DEA crackdown on physicians;  
20 correct?

21      **A.**    I don't know where -- this is not --

22      **Q.**    It's Page 5 on the right-hand side, the boldfaced  
23 heading.

24      **A.**    Page 5, right-hand side.

25      **Q.**    There is no crackdown -- no DEA crackdown on

1       physicians. That's what you were reassuring doctors of;  
2       correct?

3       **A.**     Yes.

4       **Q.**     And you've said in your testimony before Congress that  
5       doctors should not hesitate and should continue to provide  
6       patients with whatever treatment they feel appropriate as  
7       long as it's for a legitimate medical purpose and done in  
8       the usual course of medical practice; correct?

9       **A.**     That's the standard, yes.

10      **Q.**     And let's go to Page 6 in this document, Defense West  
11     Virginia 3076. In the upper left-hand corner it states, "It  
12     would be a disservice to many patients if exaggerated  
13     statements regarding the likelihood of a DEA investigation  
14     resulted in physicians mistakenly concluding that they must  
15     scale back their patient's use of controlled substances to  
16     levels below that which is medically appropriate."

17           That's a true statement; correct?

18      **A.**     Back in 2006, yes.

19      **Q.**     And just to be clear, there was an opioid crisis in  
20     2006; correct?

21      **A.**     There was, yes.

22      **Q.**     Now, you gave specific guidance in this document;  
23     correct?

24      **A.**     I'm, I'm not sure where -- if you point it to me, I'm  
25     more than happy to read it.

1       **Q.**    Sure. Let's go to Page 9, please, Defense West  
2 Virginia 3076. If we could blow up the top in the middle  
3 column, please.

4                  Do you see in the top of the middle column, if you want  
5 to read to yourself the language that precedes that in the  
6 prior column. I'm going to focus on the second line.

7                  Do you see that it says, "Courts have recognized that  
8 prescribing an inordinately large quantity of controlled  
9 substance can be evidence of a violation of the CSA."

10                 Do you see that?

11       **A.**    Yes.

12       **Q.**    And that's this idea about having exceptionally high  
13 levels; correct?

14       **A.**    Yes.

15       **Q.**    And then I want to read what you write below that if we  
16 can scroll down in this paragraph.

17                  The next paragraph begins, "Nonetheless, the amount of  
18 dosage units per prescription will never be a basis for  
19 investigation for the overwhelming majority of physicians."

20                 Do you see that?

21       **A.**    Yes.

22       **Q.**    That's a true statement; correct?

23       **A.**    Back in 2006, that was a very true statement.

24       **Q.**    Was this statement in this DEA policy statement in 2006  
25 ever repudiated on your watch?

1       **A.** Well, remember, as I said before, this is not a -- this  
2       is not just a DEA state policy statement. There were other  
3       agencies involved in this including the Department of  
4       Justice. DEA was the vehicle to get that out. If you  
5       notice, I did not sign the policy statement. It was signed  
6       by the administrator of the Drug Enforcement Administration.

7       **Q.** Do you know if DEA --

8       **A.** That was a statement.

9       **Q.** Do you know if it's ever been repudiated by DEA?

10      **A.** I never repudiated it. I have no idea if it was ever  
11       repudiated after I left.

12      **Q.** Okay. Fair enough. Let's scroll down in this  
13       paragraph. After saying that the amount will never be the  
14       basis for investigation for the overwhelming majority of  
15       physicians, if we go a sentence down, it states, "In rare  
16       cases, it is possible that an aberrant physician could  
17       prescribe such an enormous quantity of controlled substances  
18       to a given patient that this alone will be a valid basis for  
19       investigation."

20                  Do you see that statement?

21      **A.** Yes.

22      **Q.** That was true when it was made; correct?

23      **A.** It was, it was -- if it's in this document, it was true  
24       at the time.

25      **Q.** Okay. And then it gives an example. And before

1 looking at the example, let's scroll down to see what it  
2 says after the example.

3 Could we look at the sentence beginning "again" a few  
4 lines down? If you take that down and go to the middle  
5 column, please. And probably 10 lines from the bottom, four  
6 words in it begins "again, however," just above where your  
7 cursor is in the middle column. "Again, however, such cases  
8 are extremely rare." Can you cull that out?

9 Do you see where after giving this example of when  
10 levels might be excessive it says, "Again, however, such  
11 cases are extremely rare." Do you see that?

12 **A.** Yes.

13 **Q.** It continues, "The overwhelming majority of physicians  
14 who conclude that use of a particular controlled substance  
15 is medically appropriate for a given patient should  
16 prescribe the amount of that controlled substance which is  
17 consistent with their sound medical judgment and accepted  
18 medical standards without concern that doing so will subject  
19 them to DEA scrutiny."

20 Do you see that?

21 **A.** Yes.

22 **Q.** Okay. So when we were looking at this language, we  
23 skipped over the example that was given. I want to go back  
24 now to that example that was just above that.

25 And, so, this is an example of when, in the words of

1       the preceding sentence, there is such an enormous quantity  
2       of controlled substances to a given patient that this alone  
3       will be a valid basis for investigation, for example.

4                  Do you see that language?

5       **A.**   Yes.

6       **Q.**   And the example provided of when there might be -- in  
7       this 2006 DEA policy document of when there might be such an  
8       enormous quantity of controlled substances to a given  
9       patient that this alone will be a valid basis for  
10      investigation is if a physician were to prescribe 1,600  
11      tablets, and let's underline "1,600," per day, underline  
12      "per day," of a Schedule II opioid to a -- and let's  
13      underline "single patient." Do you see that?

14       **A.**   Yes.

15       **Q.**   And am I correct that this is the only example provided  
16       in this DEA policy document to doctors and the healthcare  
17       community of what constitutes such an enormous quantity of  
18       controlled substances to a given patient that this alone  
19       will be a valid basis for investigation? I don't see any  
20       other examples. Do you?

21       **A.**   I, I don't know. I'd have to go through.

22       **Q.**   If you need to look, take a look. I'm representing  
23       that there are none.

24       **A.**   Okay. Well, I trust you. Well, --

25                  (Laughter)

1                   MR. ACKERMAN: Move to strike, Your Honor.

2                   MR. SCHMIDT: I think he struck it himself, a  
3 moment of candor taken back.

4                   THE WITNESS: No, there's other, there's other  
5 examples in here. I have to read the examples, but there  
6 are other examples.

7 BY MR. SCHMIDT:

8 **Q.** Show me the examples that -- and I'm focused on  
9 something specific.

10 **A.** I know. But I don't know until I read the examples.  
11 You have the Smith example, the Bischoff example, the  
12 Poulter example, looks like Singh. So there's other,  
13 there's other examples here.

14 **Q.** Okay. And that's why I tried to tailor my question,  
15 sir.

16 **A.** Okay.

17 **Q.** See where it talks about in rare cases it is possible  
18 that an aberrant physician could prescribe such an enormous  
19 quantity of controlled substances to a given patient that  
20 this alone will be a valid basis for investigation? Do you  
21 see that?

22 **A.** No, I understand that. But I think to, to, to --  
23 without looking at these other cases, I don't know what the  
24 quantities were in these cases and I don't know what the  
25 cases -- the foundation of the cases were. So if I agree to

1       that, I mean, I don't think that would be doing the Court  
2 justice.

3       **Q.**    Fair enough. Let's stick to the example we see here on  
4 the page where it says "for example" right before saying,  
5 "Again, such cases are extremely rare."

6       **A.**    Okay.

7       **Q.**    1,600 per day for a single patient. Do you see that?

8       **A.**    Yes.

9       **Q.**    Do you know why DEA in this policy statement that you  
10 had a part in didn't say if a physician were to prescribe  
11 100 tablets per day of a single opioid to a single patient,  
12 that would certainly warrant investigation?

13      **A.**    Again, I'm not sure why this was in there.

14      **Q.**    Okay.

15      **A.**    But I can tell you the Office of Diversion Control  
16 doesn't necessarily go by quantity, but they always  
17 investigate pursuant to legitimate medical -- prescribing  
18 for a legitimate medical purpose in the usual course of  
19 professional practice.

20           And while quantity is not an issue, we do look at other  
21 factors that would open that investigation, and quantity  
22 would be part of that once the investigation is opened.

23      **Q.**    Do you know why the DEA didn't say 1,000 pills a day  
24 for a single patient would certainly warrant investigation?

25      **A.**    I don't know. But it looks like they were just looking

1 at trying to explain some egregious quantity. I don't know  
2 what the thought process was of the person that wrote this  
3 section.

4 **Q.** You agree with me that -- and I can give you a  
5 calculator if you want. If you multiply 1,600 by 365 days,  
6 by my math you get about 584,000 pills from a single doctor  
7 to a single patient in this example.

8 **A.** Well, I trust your math.

9 **Q.** Let me just check it myself just to be sure. 584 --  
10 I'm sorry. Let me do again because I might have gotten it  
11 wrong. 584,000.

12 Did you ever tell doctors -- let's take a smaller  
13 number -- that if they wrote half a million pills to a  
14 single patient in a single year that in the words of this  
15 guidance, that would certainly warrant an investigation as  
16 there is no conceivable medical basis for anyone to ingest  
17 that quantity of such a powerful narcotic? Did you ever  
18 give that guidance, that half a million instead of 584,000?

19 **A.** I'm sorry. You're going to have to repeat that.

20 **Q.** Sure. At DEA are you aware of DEA ever giving  
21 doctors -- we're talking about 584,000 pills a year here;  
22 correct?

23 **A.** Okay.

24 **Q.** Did you ever give guidance to doctors that a lesser  
25 amount, half a million pills in a year, would certainly

1 warrant investigation?

2 **A.** No, we didn't give guidance. But, obviously, 1,600  
3 pills a day is almost an impossible quantity for opioids.  
4 It is an impossible quantity. It's a ludicrous quantity.

5 So I think what they were doing was saying here's an  
6 example and just throwing up a number that is so unrealistic  
7 that no one would ever meet that.

8 **Q.** So other than giving an example that is impossible,  
9 ludicrous, and so unrealistic as what would certainly  
10 warrant investigation, is there any realistic possible  
11 non-ludicrous number that the DEA gave doctors that in the  
12 words of this policy statement from 2006 would certainly  
13 warrant investigation?

14 **A.** I'm not aware of any.

15 **Q.** Are you aware -- actually, one more thing on this  
16 document. This was a publicly available document; correct?  
17 That's why it's in the Federal Register; right?

18 **A.** Yes.

19 **Q.** If we go to Page 5, back to Page 5, 3076, Page 5, that  
20 right-hand column, I missed a sentence at the very end of  
21 the paragraph we were looking at on the right-hand side.  
22 It's the sentence before the final sentence. It's --  
23 further down, if you could just scroll down. Right there.  
24 A little, a little -- no, stop. A little up. Thanks.  
25 That's perfect.

1           Do you see where it says, where it says, "Moreover, as  
2 mentioned above, the responsibility for monitoring and  
3 preventing controlled substance abuse is shared by state and  
4 federal governments." Do you see that?

5       **A.**   Yes.

6       **Q.**   Is that a true statement?

7       **A.**   Yes.

8       **Q.**   Now, are you aware that DEA promoted pain relief at  
9 various points in time while you were there?

10      **A.**   I'm aware that -- we never promote pain relief. We  
11 just support -- we, we -- I think the statement we've used  
12 in the past was we never would want a patient to go without  
13 pain relief.

14      **Q.**   Well, let me ask you this question. Obviously, one of  
15 your goals is preventing the abuse of pain medication;  
16 correct?

17      **A.**   Yes.

18      **Q.**   Did you balance that with the policy of promoting pain  
19 relief?

20      **A.**   Again, we, we told -- we made numerous statements about  
21 that saying that patients should get the appropriate medical  
22 care to relieve their pain. We've said that over and over  
23 again.

24      **Q.**   I'm focusing on the verbiage I'm using. That was the  
25 policy of promoting pain relief; correct?

1       **A.**     It was a policy -- yeah, I guess if you want to call it  
2                  that, but it's a policy of treating pain appropriately.

3       **Q.**     Okay. And that's something -- that policy of promoting  
4                  pain relief is something you've testified about in Congress;  
5                  right?

6       **A.**     Yes.

7       **Q.**     And, so, just within this document, let's look at what  
8                  this document says on that point.

9                  If we could go to 3076, Page 4 please. And if you look  
10                 at the bottom of the left-hand column carrying over to the  
11                 center column, there's a reference to an interim policy  
12                 statement published in the Federal Register. Do you see  
13                 that?

14       **A.**     Yes.

15       **Q.**     And that's an interim policy statement from 2004 by the  
16                 DEA; correct?

17       **A.**     Yes, I -- if I'm not mistaken, that one was withdrawn  
18                 from the -- we withdrew that.

19       **Q.**     And I'm going to come to that. It says, "Chronic pain  
20                 is a serious problem for many Americans. It is crucial that  
21                 physicians who are engaged in legitimate pain treatment not  
22                 be discouraged from providing proper pain medication to  
23                 patients as medically justified."

24                  Do you see that?

25       **A.**     Yes.

1       **Q.**    Okay. And this policy statement covered a lot of  
2       things that I'm not going to go through. But I want to  
3       focus on these two sentences.

4                  Do you agree that those two sentences remained true  
5       throughout your tenure at DEA; the recognition that chronic  
6       pain is a serious problem for many Americans and that it is  
7       crucial that physicians who are engaged in legitimate pain  
8       treatment not be discouraged from providing proper  
9       medication to patients as medically justified?

10       **A.**    I agree that the second sentence is correct. The first  
11      sentence -- I believe they've made different statements  
12      about chronic pain and, and -- regarding the number of  
13      chronic pain patients and the type of pain that's chronic  
14      pain. Over the tenure that I had in the Office of Diversion  
15      Control, that's changed considerably. So I don't  
16      necessarily agree with that first statement.

17       **Q.**    Let me just show you a document, Defense West Virginia  
18      2640.

19                  MR. SCHMIDT: May I approach, Your Honor?

20                  THE COURT: It might be an appropriate time to  
21      quit if you're at a good stopping point.

22                  MR. SCHMIDT: Sure, of course, yes.

23                  THE COURT: We've got to clear things out so I can  
24      do another hearing. So we'll be in recess until 2:00.

25                  (Recess taken at 11:56 a.m.)

1                   THE COURT: Okay, Mr. Rannazzisi, you can resume  
2 your seat there, sir.

3                   MR. SCHMIDT: May I continue?

4                   THE COURT: Yes.

5                   MR. SCHMIDT: Mr. Rannazzisi, before we pick back  
6 up, two housekeeping matters.

7                   First, just if we can for you and the Court, somebody  
8 pointed out to me on the break, when I wrote this first  
9 line, supply does not drive demand, I left out the word  
10 "drive".

11                  Second, I did try to spend time over our lunch break  
12 reducing so we can get you out of here and that includes  
13 cutting out the exhibit I was about to ask you about. So,  
14 let me take up a new topic, if I could.

15                  May I approach to give out MCWV-2174?

16                  THE COURT: Yes.

17                  MR. SCHMIDT: Thank you, Your Honor.

18                  BY MR. SCHMIDT:

19                  **Q.** You have in front of you MCWV-2174?

20                  **A.** Yes.

21                  **Q.** Do you recognize this as a DEA write-up on a regulation  
22 that it was issuing during your tenure or a rule that it was  
23 issuing during your tenure?

24                  **A.** Yes.

25                  MR. SCHMIDT: We'd move this into evidence, Your

1 Honor.

2 MR. ACKERMAN: No objection.

3 THE COURT: It's admitted.

4 BY MR. SCHMIDT:

5 **Q.** Let's just orient us to what we're looking at here.

6 And before we get into this, is it correct that DEA took  
7 steps on your watch to make it easier for doctors to  
8 prescribe prescription opioids for longer periods of time  
9 without seeing the patient in between?

10 **A.** It wasn't necessarily the prescription opioids.

11 Actually, this had to do more so with patients who were away  
12 at school who were on ADHD medication, if I was not  
13 mistaken.

14 **Q.** Okay. Well, let's look at what this says. If we go to  
15 the first page, it says issuance of multiple prescriptions  
16 for controlled substances. Do you see that language in  
17 bold? And then it says agency, Drug Enforcement  
18 Administration; action, final rule. Do you see that?

19 **A.** Yes.

20 **Q.** We can actually -- I'm going to switch over on the  
21 screen, if I may, because we're done with this board.

22 And Schedule II controlled substances includes  
23 oxycodone, correct?

24 **A.** Yes.

25 **Q.** After 2014, it included hydrocodone?

1 | A. Yes.

2 Q. And this rule remained in place throughout your tenure  
3 at DEA, correct?

4 | A. Yes.

5 Q. Let's look at the summary. If we read the summary, it  
6 says the Drug Enforcement Administration is finalizing a  
7 notice of proposed rule making published in 2006. Do you  
8 see that?

9           **A.**       Yes.

10 Q. In that document DEA proposed to amend its regulations  
11 to, quote, "allow practitioners to provide individual  
12 patients with multiple prescriptions" -- and let's just  
13 highlight that language -- "allow practitioners to provide  
14 individual patients with multiple prescriptions to be filled  
15 sequentially for the same Schedule II controlled substance,  
16 with such multiple prescriptions having the combined effect  
17 of allowing a patient to receive over time up to a 90-day  
18 supply of that controlled substance." Did I read that  
19 correctly?

20            A.       Yes.

21 Q. So, in simple terms what this did is, you could go see  
22 a doctor one time and instead of having to go back within a  
23 90-day window, you could get back-to-back prescriptions to  
24 cover you for up to 90 days, correct?

25 A. That's correct.

1 Q. And that was any Schedule II controlled substance,  
2 correct?

3           **A.**       Yes.

4 Q. And that lengthened the period of time that a patient  
5 could go while having a controlled II Scheduled substance  
6 without having to see their doctor, correct?

7           **A.**       Yes.

8 Q. And this change was not limited to any specific  
9 practitioners, but applied to all DEA registered  
10 practitioners, correct?

**A.** That's correct.

12 Q. Dentists?

13 A. Well --

14 Q. General practitioners if they had a DEA registration?

15      **A.**     And if the State allowed it.

16 Q. Correct.

17 | A. Yes.

18 Q. So, let me be sure to add that. If the State allowed  
19 it and they had a DEA registration, whether they were a  
20 dentist or a general practitioner, this extension of time  
21 applied to all of them?

22           **A.**       Yes.

23 Q. Let's look at Page 7. Do you see where it says  
24 conclusion? And in the second sentence it says as DEA noted  
25 previously, this rule making was supported by a wide variety

1 of individuals and organizations, medical professionals,  
2 patient advocacy organizations, and patients themselves. To  
3 reiterate, the majority of commentators believed this final  
4 rule would be beneficial from both physical and financial  
5 perspectives, citing the time and money saved due to less  
6 frequent -- I'm sorry -- less frequent visits to prescribing  
7 practitioners, and the reduced physical toll resulting from  
8 the reduced visits. Did I read that correctly?

9 **A.** Yes.

10 **Q.** What was your role in this rule?

11 **A.** I reviewed the rule and gave my input and then it was  
12 -- subsequently went through the rule making process.

13 **Q.** Did you support it?

14 **A.** Yes, I did.

15 **Q.** And when you were saying college kids taking ADHD  
16 medications, do you understand when it references physical  
17 toll, that's talking about pain patients and prescription  
18 opioids, correct?

19 **A.** Not necessarily.

20 **Q.** Is there a physical toll from college kids having to go  
21 to their doctor?

22 **A.** Well, if they're four states over and they have to go  
23 back every month, it would be difficult.

24 **Q.** Okay.

25 **A.** But that's not the only reason. This -- this

1       supplemented what the doctors were doing to begin with,  
2       which was the doctors were prescribing huge quantities of  
3       opioids so that patients wouldn't have to come back for --  
4       every 30 days, especially palliative care, and Hospice care,  
5       end of life care. Those people can't come back every  
6       30 days.

7           So, what the doctors were doing, instead of prescribing  
8       a hundred tablets, they were prescribing 300 tablets at that  
9       moment in time. We thought that it would not be prudent to  
10      have those tablets, if the patient passed, in somebody's  
11      medicine cabinet.

12           So, if you have the do-not-fill, every 30 days it would  
13      go back to the pharmacy, and every 30 days that pharmacy  
14      would be authorized to fill. But this was all about keeping  
15      huge quantities out of prescriptions and there's no quantity  
16      limit. Congress never set a quantity limit on a Schedule II  
17      prescription. So, they could have prescribed 300 tablets  
18      easy. 400 tablets easy.

19           This cut down the amount of drugs that could be in the  
20      house at any time and made sure that the patients would be  
21      -- have access to the drugs, yet not keep a huge amount in  
22      -- in their medicine cabinets, in their homes, because of  
23      the prescriptions. And the same thing with the ADHD kids  
24      that were over at school.

25           **Q.**     So, a few follow-up questions, sir. First question,

1           this was not limited to palliative care, correct?

2       **A.**    It was not.

3       **Q.**    It did not set a pill limit to say we're going to  
4           90 days, but that means you have to have a pill limit, did  
5           it?

6       **A.**    No. There was a pill limit. It's a 30-day -- it's a  
7           90-day supply, if I'm not mistaken. So, there is a pill  
8           limit.

9       **Q.**    It was limited to 90 days, correct?

10      **A.**    Right.

11      **Q.**    It didn't limit the number of pills that could be  
12           prescribed in those 90 days, correct?

13      **A.**    Well, if it's a 90-day supply, it would be based on the  
14           way it was -- if I'm not mistaken, I haven't read this in  
15           awhile, but the way it was written, it would be per  
16           prescription. So, the quantity in the prescription, saved  
17           in the prescriptions, would dictate the amount.

18      **Q.**    There was no limit on the prescription amount that  
19           could be issued within that 90 days, correct?

20      **A.**    It's been awhile. I have not read it. But if I  
21           remember correctly, the whole reason for this was to limit  
22           the amount of drugs per prescription so the doctor wouldn't  
23           write for a 90-day supply in one prescription.

24      **Q.**    I hear what you're saying. My question is simply there  
25           was no limit in this rule on the number of prescriptions?

1           **A.** Again, if you --

2           THE COURT: Mr. Ackerman?

3           MR. ACKERMAN: Asked and answered, Your Honor.

4           MR. SCHMIDT: I don't think he's answered, Your  
5 Honor. He's explained why he was trying to do it. He  
6 hasn't answered my question.

7           THE COURT: Well, go ahead.

8           THE WITNESS: I don't -- yes, Your Honor.

9           I don't know because I haven't read this in a long  
10 time. So, I could read it and get an idea of what it says,  
11 but --

12           BY MR. SCHMIDT:

13           **Q.** All right. Let's do that. Let's go to the bottom of  
14 this page, please. And if you look at the very bottom, you  
15 can see it says Section 1306.12, very bottom, is revised to  
16 read as follows. And then it has on Page 8 the text of the  
17 language. Do you see that? Do you see that, sir?

18           **A.** Yes. I'm looking at it right now.

19           **Q.** And then, on Page 8, it has the new language of the  
20 rule. Do you see that?

21           **A.** Yes.

22           **Q.** There's no limit on pills in that new language,  
23 correct?

24           **A.** No. I believe there is a limit.

25           **Q.** Where does that appear?

1       **A.**     If you're looking for a 90-day supply, it's based on  
2     the instructions. That's why it says a 90-day supply. So,  
3     if the instructions are one tablet every -- every six hours,  
4     that would be 120 tablets. So, you would get 120 tablets  
5     per prescription.

6       **Q.**     Is there any limit here placed on the number of tablets  
7     that could be provided pursuant to an individual  
8     prescription up to 90 days?

9       **A.**     Again, it is my view and the way I looked at it was  
10    that 90-day supply was -- pertains to the amount in the  
11    prescription based on the instructions in the prescription.

12       **Q.**     Did it --

13                  MR. ACKERMAN: Your Honor, I feel like we've asked  
14    the same question and gotten the same answer now six or  
15    seven times and I -- if Mr. Schmidt doesn't like the answer,  
16    I'm sorry, but that's clearly this witness's understanding.

17                  MR. SCHMIDT: That's true that I've asked the same  
18    question and gotten the same answer. Not one of them has  
19    been responsive. But I'll move on. I think the record  
20    stands as it is and the witness is refusing to answer.

21                  MR. ACKERMAN: Move to strike that last comment.

22                  BY MR. SCHMIDT:

23       **Q.**     Let's go to Page 6. We saw on Page 7 that it talked  
24    about people in support of this change, correct?

25       **A.**     I'm sorry. Could you repeat that?

1       **Q.**    We saw on Page 7, the language we were looking at, that  
2           this regulation or this rule making talked about people who  
3           supported this change. Do you remember we read that  
4           language into the record?

5       **A.**    Yes.

6       **Q.**    There were also people who opposed it, correct?

7       **A.**    Yes. I'm sure there were. There were always people  
8           that opposed that.

9       **Q.**    Let's look at that. Third paragraph from the bottom.  
10          It says appropriateness of this rule in view of the extent  
11          of prescription controlled substance abuse in the United  
12          States. Do you see that?

13      **A.**    Yes.

14      **Q.**    And some of the commentators who objected to the  
15          proposed rule, among those, quote, "many pointed to the  
16          alarming increase in prescription controlled substance abuse  
17          in the United States and resulting deaths and harm to the  
18          public welfare." Those were comments you received opposing  
19          this lengthening of the time that doctors could give  
20          prescription opioids for without seeing their patients,  
21          correct?

22      **A.**    Yes.

23      **Q.**    And then, if we go a little further up, it says  
24          possibility of increased pressure on prescribing  
25          practitioners and it talks about some commentators and the

1 second line at the end asserting practitioners might feel  
2 undue pressure to prescribe a 90-day supply of controlled  
3 substances at each office visit. Do you see that?

4 **A.** Yes.

5 **Q.** And this rule change was made at a time you were  
6 grappling with internet pharmacies, right?

7 **A.** Yes.

8 **Q.** This rule change was made at a time that you started to  
9 see a problem with rogue pain clinics, correct?

10 **A.** There were pain clinics out there at the time, yes.

11 **Q.** And just -- quick point on rogue pain clinics. Did you  
12 ever adopt a rule or a practice where you refused to  
13 register doctors if they were in pain clinics?

14 **A.** No.

15 **Q.** Why not?

16 **A.** Because there are pain clinics that are actually not  
17 rogue.

18 **Q.** Okay. Did you ever refuse to register pharmacies that  
19 dispensed prescriptions to doctors working at pain clinics?

20 **A.** Refuse or take action against?

21 **Q.** Refuse?

22 **A.** On an application, you're talking about?

23 **Q.** Yes, sir.

24 **A.** Well, I wouldn't know if they were taking pain clinic  
25 patients unless they were actually registered to be

1 pharmacies.

2 **Q.** That's with I'm taking about. The ones that are  
3 registered as pharmacies, did you ever condition their  
4 registration on them not supplying -- filling prescriptions  
5 from doctors at pain clinics?

6 **A.** Any pharmacy registration is conditioned on the fact  
7 that if you do fill prescriptions outside the usual course  
8 of professional practice and not for legitimate medical  
9 purpose and corresponding responsibility they could have  
10 their license removed.

11 **Q.** I'm asking a little bit of a different question, sir.  
12 Did you ever make a rule that you would not register them if  
13 they filled prescriptions from any pain clinic?

14 **A.** Of course not.

15 **Q.** For the same reason you just told me about, right?

16 **A.** Yes.

17 **Q.** Now, you touched on a topic I wanted to ask you about.  
18 You agree with me that the most common, most frequent method  
19 of obtaining a pharmaceutical controlled substance for  
20 non-medical use is through friends and family for free?

21 **A.** No. I -- repeat that question again. I want to make  
22 sure I got that one right.

23 **Q.** Sure. Of course. The most frequent method of  
24 obtaining a pharmaceutical controlled substance for  
25 non-medical use is friends and family for free?

3 Q. You've also given presentations on that point, haven't  
4 you?

**A.** That's right. That's the Administration's position.

6 Q. Did you espouse any views when you were at the  
7 Administration that you believed to be false or untrue

8       **A.**     What -- to who, to the Administration?

9 Q. No, to Congress in the presentations you made on behalf  
10 of the Administration?

11       **A.**     I always presented the information that the  
12              Administration approved and that was based on a survey.  
13              That was based on a survey that I didn't necessarily agree  
14              with, but it was their position, so I was the government  
15              vehicle to get their message to Congress.

16 Q. Do you mind answering my question now, please?

17           **A.**       Yes.

18 Q. In doing that, did you ever express views you believed  
19 to be false?

20       **A.**     I -- yeah. I presented views that I didn't agree with  
21           but, I don't know if they're false or not. It was my  
22           opinion. I didn't agree with them, but --

23 Q. Okay. Well, I don't want to ask you about opinions, so  
24 I'm going to focus on truth and not truth. These views --  
25 when you expressed the view that the most frequent method of

1       obtaining a pharmaceutical controlled substance for  
2       non-medical use is friends and family for free, did you  
3       believe that was a false view?

4       **A.**      I didn't express that view. Again, again, that is the  
5       view of the Administration. When I testified before  
6       Congress, I'm not testifying as Joe Rannazzisi. I'm  
7       testifying as the Administration. When I'm going before any  
8       kind of public meeting, I'm -- I'm presenting as the  
9       Administration, not Joe Rannazzisi.

10       **Q.**      Let me come back to my question. When you testified  
11       before Congress that the most frequent method of obtaining a  
12       pharmaceutical controlled substance for non-medical use was  
13       friends and family for free, did you believe that to be a  
14       false statement?

15       **A.**      No.

16                  MR. ACKERMAN: Objection, Your Honor. Asked and  
17       answered.

18                  THE COURT: Overruled. You may answer.

19                  THE WITNESS: In my opinion, I did not agree with  
20       that. I did not agree with that statement. Do I know it's  
21       false? No. I don't know it's false, but I did not agree  
22       with that statement.

23                  BY MR. SCHMIDT:

24       **Q.**      Did you ever tell Congress I don't agree with this but  
25       this is the DEA position?

1       **A.**    That's -- that's not how congressional testimony works.  
2                    Congressional testimony, you're presenting for the  
3                    Administration for the Department of Justice.

4       **Q.**    Is the answer to my question no, you never did?

5       **A.**    No, I never did.

6                    MR. SCHMIDT: May I approach, Your Honor?

7                    THE COURT: Yes.

8                    BY MR. SCHMIDT:

9       **Q.**    I have some excerpts of a 2013 presentation with your  
10          name on it. Do you see that on the cover slide regarding  
11          drug trends?

12       **A.**    Yes.

13       **Q.**    This is excerpts. If you go to Page 2 of the document  
14          --

15                    MR. ACKERMAN: Objection, Your Honor. The problem  
16          we have is that defendants don't disclose their documents to  
17          us beforehand, so I don't know what's omitted from this  
18          document. So, I can't really object to it without finding  
19          it among a massive stack.

20                   So, I would object to questioning regarding a portion  
21          of a document that, if we can work out the excerpts before  
22          the questioning, I think that's a different story. But to  
23          just present a witness with a self-selected cherry-picked  
24          excerpt of a document is improper.

25                   MR. SCHMIDT: It's for impeachment, Your Honor.

1                   THE COURT: Yeah, overruled.

2                   BY MR. SCHMIDT:

3       **Q.** Do you see on Page 2 in this presentation you gave it  
4 says most frequent method of obtaining a pharmaceutical  
5 controlled substance for non-medical use, friends and family  
6 for free? Do you see that?

7       **A.** Yes.

8       **Q.** And do you know if you gave that -- made that statement  
9 at presentations more than once?

10      **A.** Yes. That was the Government's position.

11      **Q.** At any of those presentations did you say this is the  
12 Government's position, but my opinion, I disagree with it?

13      **A.** I wouldn't do that. That's not what we're allowed to  
14 do.

15      **Q.** Did you believe you were saying something false when  
16 you said this?

17      **A.** No. I -- as I said before, I didn't agree with it, but  
18 they had a survey to back it up, so I didn't have a choice  
19 but to go with it.

20      **Q.** Do you have any contrary data?

21      **A.** Yeah, our investigations.

22      **Q.** I mean like a study or a survey?

23      **A.** No. Just our investigations.

24      **Q.** And then the next slide says medicine cabinet and then  
25 problem, pharmaceutical controlled substance disposal. Do

1 you see that?

2 **A.** Yes.

3 **Q.** And then it says so many drugs in the household, why,  
4 and then it gives two reasons. Do you see that?

5 **A.** Yes.

6 **Q.** One is unreasonable quantities being prescribed. Do  
7 you see that?

8 **A.** Yes.

9 **Q.** And that refers to decisions being made by doctors,  
10 correct?

11 **A.** Yes.

12 **Q.** And do you believe that to be true, that some of the  
13 contributions to unreasonable levels of drugs in the  
14 household is unreasonable quantities being prescribed?

15 **A.** Yes.

16 **Q.** And just to be clear, what I understand you to be  
17 talking about here is that if -- and I think you touched on  
18 it in the context of that 90-day rule, that if you have a  
19 lot of opioids given to a given patient, someone else might  
20 use them?

21 **A.** Yes.

22 **Q.** Someone might take them. They might steal them. They  
23 might give them away. And that can be -- that is diversion?

24 **A.** Well, technically, yes.

25 **Q.** Every one of those is diversion, right, stealing,

1 giving away, selling?

2 **A.** Well, if it's in the patient's hands, once it's in the  
3 patient's hands, if it's stolen, it's just -- it's stolen.  
4 It's not necessarily diversion.

5 **Q.** Okay, fair enough.

6 **A.** Because the patient is not within the closed system of  
7 distribution.

8 **Q.** And that form of diversion or theft can occur even if a  
9 distributor, or a pharmacy, or a manufacturer does what  
10 they're supposed to do, right? They could fill a good faith  
11 prescription written for an unreasonable quantity, or even a  
12 reasonable quantity, and some could be stolen, given away,  
13 sold?

14 **A.** What did you say initially? Just -- I didn't hear the  
15 first part of the question.

16 **Q.** The first part of my question was you can have a  
17 prescription written in good faith where, as to that  
18 prescription, the doctor does what they're supposed to do,  
19 the pharmacy does what they're supposed to do, the  
20 distributor does what they're supposed to do, and the  
21 manufacturer does what they're supposed to do, and it still  
22 gets sold, stolen or given away?

23 **A.** Yes.

24 **Q.** The second point you have on this slide is insurance  
25 rules. Do you see that?

1       **A.**     Yes.

2       **Q.**     What are you referencing there?

3       **A.**     Some insurance companies require a 90-day supply,  
4       60-day supply, depending on the insurance company for  
5       filling, but not necessarily controlled substances.

6       **Q.**     And, actually, one more question about this document.

7       I apologize. I want to make sure I just have this.

8               When you told Congress and others that the most  
9       frequent method of obtaining a pharmaceutical controlled  
10      substance for non-medical use was friends and family for  
11      free, you understood that to be the position of the DEA,  
12      correct?

13      **A.**     It was the position of the Administration so, yes.

14      **Q.**     In making public statements about prescription opioids,  
15      there were occasions where you would refer doctors to  
16      standards adopted by their State Medical Boards, correct?

17      **A.**     We always refer the doctors to their State Medical  
18      Boards because only the states dictate the practice of  
19      medicine.

20      **Q.**     In fact, you took the position that the DEA encourages  
21      physicians to seek guidance from the State Medical Boards,  
22      correct?

23      **A.**     Again, yes. The states dictate the practice of  
24      medicine. So, yes, that's been said before.

25               MR. SCHMIDT: And I didn't ask to approach. I'm

1 sorry, Your Honor.

2 BY MR. SCHMIDT:

3 Q. Do you recognize Exhibit P-9270 as an article that you  
4 wrote that was published in June of 2000 in a publication  
5 called Clinical Pharmacology and Therapeutics? My question,  
6 sir, simply is do you recognize this article as an article  
7 you have written?

8 A. I wrote a lot of articles. My name is on it, so I'm  
9 sure I wrote it, but I just don't recall this one.

10 MR. SCHMIDT: We'd move into evidence Exhibit  
11 P-09270.

12 MR. ACKERMAN: Can I have a minute to consult with  
13 my colleagues, Your Honor?

14 THE COURT: I'm sorry?

15 MR. ACKERMAN: I just need to minute to consult  
16 with my colleagues.

17 THE COURT: Yes. Yes.

18 MR. SCHMIDT: And if I can just ask one question  
19 while you're consulting, just for the record.

20 BY MR. SCHMIDT:

21 Q. If you look at the bottom, do you see under your name  
22 it says -- it's not just any J. T. Rannazzisi. It's J. T.  
23 Rannazzisi from the Office of Diversion Control Drug  
24 Enforcement Administration, Alexandria, Virginia. Do you  
25 see that?

1           **A.**     Yes.

2           **Q.**     And there's a DEA -- I guess it's an e-mail address  
3                 where you --

4                 MS. SINGER: Excuse me, Mr. Schmidt. Could you  
5                 just give us one minute before you ask the question?

6                 MR. SCHMIDT: Yes. Sure. Of course.

7                 MS. SINGER: Thank you.

8                 (Pause)

9                 MR. ACKERMAN: So, Your Honor, we have no  
10                 objection to introducing medical literature provided that we  
11                 are afforded the same courtesy.

12                 MR. SCHMIDT: I don't see how --

13                 THE COURT: That depends entirely on what the  
14                 medical literature is, Mr. Ackerman.

15                 MR. ACKERMAN: I understand. We have no objection  
16                 to this document.

17                 MR. SCHMIDT: Okay.

18                 THE COURT: You want it admitted, Mr. Schmidt?

19                 MR. SCHMIDT: Yes, please, Your Honor.

20                 THE COURT: All right. It's admitted.

21                 BY MR. SCHMIDT:

22                 **Q.**     All right. So, let's just look at that language that I  
23                 was reading you. It was on the right-hand side. Do you see  
24                 where you wrote in this article, this is a pharmacology and  
25                 therapeutics article, that the DEA encourages physicians to

1 seek guidance from their State Medical Boards? That's that  
2 proposition we've been discussing, correct?

3 **A.** Yes. We've gone over that in the past, yes.

4 **Q.** And that's something you did throughout your career at  
5 DEA, correct?

6 **A.** When speaking to physicians groups, yes.

7 **Q.** Let's look at an example of that.

8 MR. SCHMIDT: Your Honor will recall that we used  
9 a book earlier and I believe Mr. Hester promised we would  
10 give the Court a hard copy of the book, so I want to carry  
11 through on that promise, if I may.

12 THE COURT: Yes. I would like to have some more  
13 things up here.

14 MR. SCHMIDT: This one is slender. It's MCWV-2111  
15 and it's in evidence.

16 And then there's paper copies if anyone wants a paper  
17 copy of the pages.

18 BY MR. SCHMIDT:

19 **Q.** There's been testimony in this case that this book was  
20 sent by the Medical Boards of 13 states, including West  
21 Virginia, to every doctor in those 13 states, including West  
22 Virginia. Is that something that you were aware of when you  
23 told doctors to look to the guidance they received from  
24 State Medical Boards?

25 **A.** I know this book has been used in certain areas of the

1       country. I didn't know that the Medical Boards were sending  
2       the books to all the doctors.

3       **Q.**     Okay. But you knew it was being used?

4       **A.**     This book?

5       **Q.**     Yes.

6       **A.**     This book has been around for awhile, yes, sir.

7       **Q.**     And I didn't give you a hard copy. I apologize for  
8       that. Do you want my copy or do you want a paper copy? I  
9       can give you just --

10      **A.**     A paper copy is fine.

11      **Q.**     Okay.

12                  THE COURT: He can have mine, Mr. Schmidt.

13                  MR. SCHMIDT: We desperately want Your Honor to  
14       have it.

15                  BY MR. SCHMIDT:

16      **Q.**     All right. Let's just look at a couple of pages of  
17       this. If we go to Page 9 of the book, which is Document  
18       Page 15, do you see in the upper right corner there's some  
19       bullets? Tell me when you're there, sir.

20      **A.**     I'm on Page 15.

21      **Q.**     You see the first bullet says patients should not be  
22       denied opioid medication except in light of clear evidence  
23       that such patients [sic] are harmful -- such medications are  
24       harmful to the patients? Do you see that language?

25      **A.**     Yes.

1       **Q.**   Were you aware at the time you referred doctors to  
2           State Medical Boards that statements like this were being  
3           sent by Medical Boards to doctors in at least 13 states?

4           MR. FARRELL: Objection, Your Honor. I think that  
5           misstates the testimony.

6           THE COURT: Overruled.

7           BY MR. SCHMIDT:

8       **Q.**   Were you aware of that, sir?

9       **A.**   No. Like I said, I wasn't aware that this book was  
10          being passed out by the Medical Boards.

11       **Q.**   Okay. Go to Page 94 of the book. Do you see where  
12          there's a heading Federal Guidelines For Prescribing  
13          Controlled Substances? Do you see that heading?

14       **A.**   Yes.

15       **Q.**   And do you see -- if you just kind of scroll through  
16          there, do you see reference to the 2006 policy statement  
17          that you spent some time talking about earlier today?

18       **A.**   Yes.

19       **Q.**   And then if we continue on to the next page, Page 95,  
20          do you see that there's -- this came out before the 90-day  
21          rule we were just talking about was finalized, but do you  
22          see there's discussion of that rule being proposed?

23       **A.**   Okay.

24       **Q.**   Now, you said -- I'm not going to go through the rest  
25          of this book. I'm going to wrap up just with a couple of

1           questions.

2           When you were at DEA, you said you knew about this  
3       book. Did you ever -- you or your colleagues at DEA ever  
4       issue any kind of statement correcting anything you believed  
5       to be wrong in this book?

6       **A.** No. DEA did not get involved in medical practice.

7       **Q.** Do you see on the cover it says Federation of State  
8       Medical Boards?

9       **A.** Yes.

10      **Q.** On multiple occasions you've relied on guidelines from  
11       the Federation of State Medical Boards, correct?

12      **A.** Yes.

13      **Q.** And, in fact, one of those occasions is actually  
14       referring to distributors to the Federation of State Medical  
15       Boards, correct?

16      **A.** I'd have to see it.

17      **Q.** All right.

18      **A.** Referring to the internet pharmacy? I don't -- I would  
19       have to see what you're referring to.

20      **Q.** Fair enough. Let me help you out. Let's pull up  
21       P-1205, which is in evidence. I think it is a document you  
22       were shown, so you should have it in your stack, and it is  
23       the distributor slides. And let's go to Page 9 of that  
24       document.

25           And do you see that there is reference to -- in giving

1 guidance to distributors, there's reference to the  
2 Federation of State Medical Boards as something distributors  
3 can look to in understanding medical need?

4 **A.** Okay.

5 **Q.** That's guidance you gave to distributors about  
6 understanding medical need, correct?

7 **A.** Yeah. Because we're talking about the model guidelines  
8 of internet, yes.

9 **Q.** I want to touch very quickly on the other participants  
10 in the closed system starting with pharmacies. Pharmacies  
11 are also required to have a DEA registration, correct?

12 **A.** Yes.

13 **Q.** They're also required to renew it periodically?

14 **A.** Yes.

15 **Q.** Why is that?

16 **A.** Again, every three years so we can do background and  
17 make sure that they are indeed licensed appropriately and  
18 have not had any disciplinary action.

19 **Q.** Are you aware of any instance from your work at DEA  
20 where any one of the three distributors in this case  
21 supplied controlled substances to a Huntington or Cabell  
22 County pharmacy that was not registered with the DEA?

23 **A.** No.

24 **Q.** Are you aware of any instances from your tenure at DEA  
25 where one of the defendants supplied prescription opioids to

1       a DEA licensed pharmacy in Huntington or Cabell that the DEA  
2       had warned the distributor not to supply?

3       **A.**     Not that I'm aware of.

4       **Q.**     You talked for a bit yesterday about whether  
5       distributors should require certain information from  
6       pharmacies or not do business with them. Do you remember  
7       that?

8       **A.**     Yes.

9       **Q.**     Have you ever made it a condition for registration of  
10      pharmacies that in order to be registered they had to give  
11      distributors certain categories of information?

12      **A.**     No.

13      **Q.**     For example, did you ever say if you're going to be  
14      registered as a pharmacy, you've got to share dispensing  
15      data or doctor information with distributors?

16      **A.**     No, we didn't tell them that.

17      **Q.**     Did you ever tell distributors as a condition of  
18      registration that they had to get that kind of data from  
19      every pharmacy or refuse to do business with them?

20      **A.**     No. That would be part of their due diligence. That's  
21      up to them.

22      **Q.**     Let's talk about manufacturers. DEA must also register  
23      manufacturers for them to be able to make controlled  
24      substances, correct?

25      **A.**     Yes.

1       **Q.**    Manufacturers are the ones responsible for studying the  
2           safety and the benefits of prescription opioids and other  
3           medications that they make, correct?

4       **A.**    Yes.

5       **Q.**    And they're the ones who obtain FDA approval for new  
6           prescription opioids, correct?

7       **A.**    Yes.

8       **Q.**    And I'm not going to ask you too much about the FDA,  
9           but do you have an understanding that at least when it came  
10          to prescription opioids, the FDA was only supposed to  
11          approve a prescription opioid if they determine that the  
12          benefits outweigh its known and potential risks for the  
13          intended population?

14                    MR. ACKERMAN: Objection to scope, Your Honor.

15                    This is --

16                    THE COURT: Overruled.

17                    BY MR. SCHMIDT:

18       **Q.**    Do you want me to re-ask it?

19       **A.**    The FDA's approval process is on safety and efficacy.

20       **Q.**    And they've got to determine that the safety -- that  
21          the benefits outweigh the risks, right?

22       **A.**    I believe that's built into it, safety and efficacy,  
23          yes.

24       **Q.**    Are you aware that the physician warnings that  
25          manufacturers were required to provide for the prescription

1       opioids warned doctors that they had a risk of abuse and  
2       addiction?

3       **A.**     In the literature? I'm sure it's in there, yes.

4       **Q.**     Are you aware of any distributor in this case that  
5       distributed opioids in Huntington or Cabell that were not  
6       approved by the FDA?

7       **A.**     I'm not aware of any.

8       **Q.**     Are you aware of an instance where the DEA ever told a  
9       distributor in this case not to do business with the DEA  
10      registered manufacturer?

11      **A.**     I -- I don't have any information on that.

12      **Q.**     Okay. Let me ask you just a few more questions on  
13      distributors and then I'll turn to a different topic.

14                  Distributors aren't authorized to write prescriptions,  
15      correct?

16      **A.**     That's correct.

17      **Q.**     They don't evaluate a patient's legitimate medical need  
18      for opioids in terms of deciding whether the opioids are  
19      appropriate for that patient, correct?

20      **A.**     That's correct.

21      **Q.**     They can't second-guess legitimate medical decisions by  
22      prescribers, correct?

23      **A.**     I don't understand when they would be questioning a  
24      legitimate medical prescription.

25      **Q.**     And they don't have access to individual patient

1 medical records because of privacy laws, correct?

2 **A.** They wouldn't have access to that.

3 **Q.** There's been discussion in this case about a term "know  
4 your customer's customer". That's not a term you were  
5 familiar with during your time with DEA, correct?

6 **A.** No. "Know Your Customer", not "Know Your Customer's  
7 Customer".

8 **Q.** You recognize that distributors play an important role  
9 in insuring an adequate and uninterrupted supply of  
10 prescription opioids?

11 **A.** Yes.

12 **Q.** It's important -- it's an important role in terms of  
13 them being able to move those drugs downstream and ensure  
14 that pharmacies and hospitals have those drugs, correct?

15 **A.** Yes.

16 **Q.** And that's important because if a patient doesn't get  
17 the medication they need, there's a breakdown in the system,  
18 correct?

19 **A.** Yes.

20 **Q.** And that role is a similar role, or a similar interest,  
21 a similar purpose, to the DEA in ensuring an adequate  
22 supply, correct? Distributors are part of that process of  
23 ensuring an adequate supply?

24 **A.** Yes.

25 **Q.** You agree that it's critical for patients who have a

1       medical need for prescription opioids to have access to  
2       them?

3       **A.**     Yes.

4       **Q.**     A couple small points. During your ten years at DEA,  
5       you never told distributors to retain due diligence files on  
6       all of their customers for all time, correct?

7       **A.**     I personally did not, no.

8       **Q.**     You can't identify anyone at DEA who told that to  
9       distributors, correct?

10      **A.**     No. It's just common sense that if they're doing due  
11       diligence and they're maintaining files, they would maintain  
12       files for the duration of that customer's business  
13       relationship so they could see and reach back and look at  
14       what the prescribing patterns were from the beginning all  
15       the way up to the present.

16      **Q.**     While you were at DEA you recognized that ARCOS data  
17       was helpful to the agency in generating leads for  
18       investigations, correct?

19      **A.**     Yes.

20      **Q.**     Registrants requested ARCOS data from DEA, but DEA  
21       declined to share it, correct?

22      **A.**     Yes. We were -- we were instructed that we could not  
23       share it, yes.

24      **Q.**     Do you know that DEA has not been required to give  
25       distributors limited access to ARCOS?

1       **A.**     I do from the deposition, the last deposition, yes.

2       **Q.**     Did you ever support giving distributors more access to  
3           ARCOS than they were allowed or the access that they enjoy  
4           today?

5       **A.**     It wasn't a question of whether I supported it or not.  
6           It's a question of what I was allowed to do during my tenure  
7           and the answer is no.

8       **Q.**     Did you ever take steps to try to grant greater access?

9       **A.**     Again, we're getting into internal deliberate process  
10          about what we can and can't do.

11       **Q.**     All I'm asking you, sir, is if you took any such steps.  
12          I don't want to hear about discussions with people.

13       **A.**     We --

14       **Q.**     I want to know -- let me finish, please. I just want  
15          to know if you took any steps to try to grant greater access  
16          to ARCOS data when you were at DEA?

17                   MS. SINGER: Objection, Your Honor. I think this  
18          is the same issue that defendants were raising yesterday if  
19          we can't probe on redirect the reasons for any decision  
20          making that leads to an unbalanced and unfair situation  
21          where they illicit testimony that can't be fully explored.

22                   THE COURT: Well, the question was if he took any  
23          steps to try and grant greater access to ARCOS. I'm going  
24          to let him answer that question.

25                   THE WITNESS: I personally did not take any steps.

1 BY MR. SCHMIDT:

2 Q. I'm going to close out with one topic. I want to talk  
3 about some of those DEA powers that you talked about in your  
4 direct examination. And I want to actually put something in  
5 front of you and ask you about it, if I can, because it will  
6 frame some of my questions a little more easily.

7 MR. SCHMIDT: May I approach, Your Honor?

8 THE COURT: Yes.

9 MR. SCHMIDT: For the record, this is MCWV-1081.  
10 It's testimony from July, 2006 before the Subcommittee on  
11 the House of Representatives. Do you see that?

12 A. Yes.

13 Q. And if you go to Page 61 -- I'm sorry -- actually, 63  
14 in the lower corner. Wait. 65, I'm sorry. 65 in the lower  
15 left corner. Do you see that?

16 A. That's Page 65.

17 Q. Do you see your prepared statement?

18 A. Yes.

19 Q. All right. I'd like to look at Page 72, please, in the  
20 lower left corner within your prepared statement. And  
21 here's what I would like to ask you about, sir.

22 A. Okay.

23 Q. It says in the third full paragraph, do you see where  
24 it says the CSA, the Controlled Substances Act, includes  
25 seven major controlled mechanisms? Do you see that?

1       **A.** Yes.

2       **Q.** And then it lists them. Do you see that?

3       **A.** Yes.

4       **Q.** And is that an accurate list of different control  
5       mechanisms that the CSA grants the DEA?

6       **A.** No. That -- that seems to be accurate.

7       **Q.** Okay. First one is scheduling. That's Schedule II,  
8       III, IV, et cetera?

9       **A.** Yes.

10      **Q.** And the second one is registration, correct?

11      **A.** Yes.

12      **Q.** And that's registration of all the participants in the  
13       closed system, correct?

14      **A.** Yes.

15      **Q.** I'm going to skip a couple. The last one is  
16       investigational authority, correct?

17      **A.** Yes.

18      **Q.** And then if you go to actually the third one, it's  
19       quotas, correct?

20      **A.** Yes.

21      **Q.** And then you talked yesterday and we talked a little  
22       bit today about your power to enact regulations when  
23       appropriate, correct?

24      **A.** Yes.

25      **Q.** And you can also give guidance, correct?

1       **A.** Yes.

2       **Q.** All right. I want to ask you about those four points,  
3 please. Before I leave this document, if we look at the  
4 next sentence, these mechanisms allow DEA to monitor and  
5 regulate a controlled substance and its movement. Do you  
6 see that?

7       **A.** Yes.

8       **Q.** Is that true?

9       **A.** Yes.

10      **Q.** In the case of the most potentially dangerous drugs in  
11 Schedule II, we register all persons who handle them. We  
12 inspect the documentation of their distribution. We control  
13 their import and export. And we control the amount  
14 produced, bought, sold, and otherwise transferred. Do you  
15 see that?

16      **A.** Yes.

17      **Q.** And all of that is true, correct?

18      **A.** Yes.

19      **Q.** So, let's go through those categories very quickly.

20      **A.** Okay.

21      **Q.** First, registration. And I can show you that there's  
22 -- this information. Are you aware that the DEA website  
23 tracks the number of registered pharmacies, registered  
24 practitioners, over time?

25      **A.** I've seen slides to that effect, but I haven't seen

1                   them in awhile, so --

2       **Q.**    Do you take any issue with the fact that the number of  
3                   DEA registrations issued to pharmacies in West Virginia went  
4                   up by about a hundred between -- or 20 percent between 2005  
5                   and 2015?  Do you take any issue with that?

6       **A.**    I wouldn't know.

7       **Q.**    Okay.  Well, let me show you then.

8                   MR. SCHMIDT:  And may I approach, Your Honor?  Two  
9                   single page documents.

10                  BY MR. SCHMIDT:

11       **Q.**    Mr. Rannazzisi, Exhibit MCWV-2183 is a printout from  
12                  the Diversion Control Division Registration -- Registrant  
13                  Population by State and Business.  Do you see that?

14       **A.**    Yes.

15       **Q.**    And it allows you to select a state that that box that  
16                  says West Virginia and it allows you to select a time  
17                  period.  It looks like we actually chose later, August --  
18                  August, 2006.  Do you see that?

19       **A.**    Yes.

20       **Q.**    And there's 513 DEA registered pharmacies.  Do you see  
21                  that?

22       **A.**    Yes.

23       **Q.**    And 5,446 DEA registered practitioners.  Do you see  
24                  that?

25       **A.**    Yes.

1       **Q.**   If you go to the next slide, or the next document,  
2 MCWV-2197, it's the same web page, also for West Virginia,  
3 this time for October, 2015. And do you see that the  
4 pharmacies have gone from 513 to 600, nearly a hundred?

5       **A.**   Okay.

6       **Q.**   And that practitioners have gone from 5,446 to 6,656,  
7 more than a thousand? Do you see that?

8       **A.**   Yes.

9                   MR. SCHMIDT: We'd move these two into evidence,  
10 Your Honor.

11                  THE COURT: Any objection?

12                  MR. ACKERMAN: No objection.

13                  THE COURT: They're both admitted.

14                  BY MR. SCHMIDT:

15       **Q.**   My question on this to you simply is I take it your  
16 judgment at DEA was that that increase in both pharmacy and  
17 doctor registrations both by somewhere in the order of  
18 20 percent was appropriate given medical needs and  
19 legitimacy of those pharmacies --

20                  THE COURT: Let me interrupt and ask you a  
21 question. What's a mid-level practitioner on that chart?

22                  THE WITNESS: Your Honor, that would be a  
23 physician's assistant, advanced practice nurse, and certain  
24 -- podiatrists.

25                  THE COURT: And they're authorized under some

1                   circumstances to prescribe opioids?

2                   THE WITNESS: Yes, sir. The way -- the way that  
3                   the Controlled Substances Act works is we look to the State.  
4                   If the State grants them the ability to prescribe controlled  
5                   substances, we're required -- unless they have some kind of  
6                   felony in their background, we're required to give them a  
7                   license.

8                   BY MR. SCHMIDT:

9                   **Q.** And just to complete the record, that category for  
10                  mid-level practitioners, more than doubled from 910 to  
11                  2,023, correct?

12                  **A.** Yes.

13                  **Q.** I take it you had view that this growth in  
14                  registrations from mid-level practitioners, practitioners  
15                  and pharmacies was appropriate?

16                  **A.** Well, the State dictates the practice of medicine, the  
17                  practice of pharmacy, and the oversight of the mid-level.  
18                  So it's what the state believes is appropriate, not what DEA  
19                  believes.

20                  **Q.** Well, in terms of DEA granting them a separate  
21                  registration, did DEA believe it was appropriate to  
22                  separately register them under its standards?

23                  **A.** As long as they met the appropriate licensure  
24                  requirements under the State, DEA has really no choice but  
25                  to -- to register them.

1       **Q.**   I want to focus on -- we -- you and I talked earlier  
2       about the .01 percent of the doctors that DEA takes action  
3       against on an annual basis. Yesterday you were asked about  
4       16,000 doctors. Do you remember that testimony?

5       **A.**   Yeah. I think it was a range, but --

6       **Q.**   Yeah. You agree that it's a good thing to require DEA  
7       criminal background investigations of all new registrant  
8       applications, correct?

9       **A.**   There should be a background investigation done, yes.

10      **Q.**   There was a period of time where you didn't do any  
11       background checks either with the initial registration of a  
12       prescriber or subsequent registration of a prescriber,  
13       correct?

14      **A.**   There was a time where we -- there was a time where we  
15       were not given access to certain databases and we had to go  
16       through private -- private means to get that background  
17       information, yes.

18      **Q.**   Well, I think that's a little different than what I  
19       asked. Let me try one more time.

20           Did there come a point in time where you didn't do any  
21       background checks either with the initial registration of a  
22       prescriber or a subsequent registration of a prescriber?  
23       Yes or no, if you can?

24      **A.**   I don't recall. I -- I know there was a time where  
25       there was an issue with that. I just don't recall the exact

1 time and the length of that time.

2 **Q.** Can we cull up the July 16th, 2020 transcript at Page  
3 129, Lines 2 through 7?

4 MR. ACKERMAN: For the record, Your Honor, we'd  
5 renew our objection to use of this transcript, which is not  
6 the MDL transcript.

7 THE COURT: All right. Overruled.

8 BY MR. SCHMIDT:

9 **Q.** Question, then there came a point in time where you  
10 didn't do any background checks, either with initial  
11 registration of a prescriber or subsequent registration of a  
12 prescriber, correct? And your answer was no. We relied on  
13 the State. Did I read that correctly?

14 **A.** Yes. And I said we relied on the State, but there were  
15 other things that occurred, but that's -- that's absolutely  
16 correct. We did rely on the State.

17 **Q.** And you're aware of government findings from after your  
18 watch that you relied on the good faith of applicants to  
19 disclose relevant information, correct?

20 **A.** Yes.

21 **Q.** And that's a true statement, that you relied on the  
22 good faith of applicants to disclose relevant information,  
23 correct?

24 **A.** And the State, yes.

25 **Q.** Do you know with specificity what types of background

1 checks West Virginia did?

2 **A.** I don't know.

3 **Q.** Let me ask you, does prescriber registration from the  
4 DEA, in your view, provide meaningful protection to the  
5 public against improper prescribers?

6 **A.** Yes.

7 **Q.** Let's go to the second category, investigations. Do  
8 you know there are times where distributors told the DEA  
9 they were cutting off pharmacies, correct?

10 **A.** I'm sorry. Can you repeat, please?

11 **Q.** Of course. Do you know there are times, occasions,  
12 when distributors told the DEA that they were cutting off  
13 pharmacies, correct?

14 **A.** Yes.

15 **Q.** And of the instances where that happens, you don't know  
16 what percentage of those pharmacies DEA actually  
17 investigated, correct?

18 **A.** No. As I sit here, no.

19 **Q.** You can't tell me if it was 10 percent, 50 percent, 1  
20 percent, correct?

21 **A.** I don't know.

22 **Q.** You can't tell me what percentage of the tens of  
23 thousands of suspicious orders that DEA received on your  
24 watch that actually directly led to an investigation,  
25 correct?

1       **A.**    I don't -- I don't know and I don't think I could -- I  
2           don't think I could tell you that even if I did know.

3       **Q.**    Okay. I'll stand on your you don't know. Do you know  
4           whether it was more than one percent of suspicious orders  
5           reported that resulted in an investigation? Do you know?

6       **A.**    I don't know.

7       **Q.**    Okay. Can you identify any suspicious orders reported  
8           for pharmacies in Huntington or Cabell? And I don't want  
9           you to tell me which ones, but can you any that resulted in  
10          investigations?

11       **A.**    I don't know.

12       **Q.**    You're aware that DEA has been criticized for its use  
13          of Suspicious Order Reports that have been submitted by  
14          distributors, correct?

15       **A.**    Could you repeat that, please?

16       **Q.**    Are you aware that DEA has been criticized by the  
17          Office of the Inspector General for its use of suspicious  
18          orders submitted by distributors?

19       **A.**    Can you tell me which report you're referring to? Is  
20          that the 2019 report?

21                   THE COURT: Just a minute.

22                   Mr. Ackerman?

23                   MR. ACKERMAN: Actually, let the witness clarify  
24          first because I think that will explain my objection.

25                   THE COURT: All right.

1 THE WITNESS: 2019 report?

2 MR. SCHMIDT: Yes.

3 MR. ACKERMAN: All right. So, Your Honor, counsel  
4 is now beginning to question regarding a 2019 Office of the  
5 Inspector General Report. That report was issued after the  
6 MDL deposition. It was not addressed in the MDL deposition.  
7 So, we'd offer our scope objection consistent with your  
8 ruling on the permissible scope of Mr. Rannazzisi's  
9 testimony with respect to this line of questioning.

10 MR. SCHMIDT: It relates to his tenure, sir.

11 THE COURT: Pardon me?

12 MR. SCHMIDT: It relates to his tenure, Your  
13 Honor.

14 THE COURT: Yes. Overruled. This is cross  
15 examination. I'm going to allow it.

16 By MR. SCHMIDT:

17 Q. Are you aware of that 2019 report that takes issue with  
18 how DEA dealt with Suspicious Order Reports on your watch?

19 A. I remember there was a section in there about  
20 suspicious orders, yes.

21 Q. And one of the findings from that report, do you  
22 recall, is that DEA Field Division staff did not receive  
23 access to the Suspicious Order Reporting System until 2017,  
24 after your tenure; do you recall that?

25 A. No. I -- if you can --

1           **Q.**    Of course.

2           **A.**    I would like to read that.

3                   MR. SCHMIDT: May I approach, Your Honor?

4                   THE COURT: Yes.

5                   MR. SCHMIDT: This is in evidence.

6                   MR. FARRELL: Judge, on behalf of Cabell County  
7 and to save us some time, does this open the door for  
8 re-direct on this document with this witness?

9                   THE COURT: Well, we'll cross that bridge when we  
10 get to it, Mr. Farrell.

11                  MR. FARRELL: Thank you.

12                  BY MR. SCHMIDT:

13           **Q.**    And do you recognize this document as the one we've  
14 been discussing?

15           **A.**    Yes.

16           **Q.**    And if you look on Page 36, it says in the middle  
17 paragraph five lines, six lines, seven lines down, one  
18 diversion program manager.

19                  MR. SCHMIDT: Can you highlight that language from  
20 the middle paragraph, please?

21                  BY MR. SCHMIDT:

22           **Q.**    Described the SORS database as a "joke", noting that  
23 DEA Field Division staff did not receive access to the SORS  
24 database until 2017, nearly ten years after it was created.  
25 Are you aware of that finding?

**A.** I'm sorry. Which page are we on here?

2 Q. It's little numbered Page 36.

3 | A. 36?

4 Q. In the lower left. Were you aware of that finding,  
5 sir?

8 Q. Your understanding is that when there was follow-up on  
9 Suspicious Order Reports it would be done by the local Field  
10 Office agents, correct?

11           **A.**       Yes.

12 Q. Are you aware of any suspicious orders -- well, I think  
13 I probably asked this.

14 Let's move to the next category. And I'm actually  
15 going to jump to number 4, regulations and guidance.

16 Could we cull out P-34, which is a copy of your 2007  
17 letter? And I'm just going to point you to specific  
18 language. If we go to the second paragraph of your letter  
19 and the second last sentence. Accordingly, DEA does not  
20 approve -- wrong sentence. The one before, please.

21           Accordingly, DEA does not approve or otherwise endorse  
22 any specific system for reporting suspicious orders. Do you  
23 see that?

24           **A.**       Yes.

Q. That was your view throughout your tenure at DEA,

1                   correct?

2         **A.**    Yes.

3         **Q.**    Are you aware of any of your predecessors stating that  
4                   view in writing in a document you could point us to?

5         **A.**    I -- I don't -- I can't recall if there was or was not.

6         **Q.**    Now, let me focus on your watch, 2005 to 2015. I  
7                   believe you've covered this, but I need to make sure I've  
8                   covered it. On your watch you made clear that how a  
9                   distributor created a Suspicious Order Monitoring System was  
10                  for them to figure out, correct?

11        **A.**    They were required to create their own system, yes.

12        **Q.**    You refused to approve individual suspicious order  
13                  monitoring systems, correct?

14        **A.**    We weren't authorized to approve suspicious order  
15                  monitoring systems.

16        **Q.**    While you were at the DEA you took the position that it  
17                  was up to the distributors to figure out whether an  
18                  individual order was suspicious or not, right?

19        **A.**    It was up to the distributor to determine what's  
20                  suspicious and what's not.

21        **Q.**    You took the position that it was up to the distributor  
22                  to figure out whether to ship an order or not, correct?

23        **A.**    That's correct.

24        **Q.**    And you took the position that it's up to the  
25                  distributor to figure out whether to increase thresholds for

1 individual pharmacies, correct?

2 **A.** We never talked about thresholds with the distributors.

3 It's not -- it was the position of the Drug Enforcement  
4 Administration. All of these things that you just mentioned  
5 were the Drug Enforcement Administration's position.

6 **Q.** That they had figure out their own thresholds, correct?

7 **A.** Yes.

8 **Q.** You never told distributors that if you take specific  
9 steps in your diligence programs, that would be compliant,  
10 correct?

11 **A.** I don't follow your question.

12 **Q.** Did you ever say to distributors if you take these  
13 specific steps in your diligence, that will be compliance?

14 **A.** No.

15 **Q.** You never told distributors that if you used these  
16 criteria to try to assess suspicious orders and anytime you  
17 see an order that triggers these criteria and you report it  
18 to the DEA, you will be meeting your suspicious order  
19 reporting obligations, correct?

20 **A.** I don't recall saying that.

21 **Q.** And I think you touched on this yesterday. You had a  
22 policy of not sharing with distributors when you were  
23 investigating a pharmacy customer of theirs, correct?

24 **A.** We're not authorized to share investigative  
25 information.

1 Q. And I think you said due process concerns for the  
2 pharmacy, correct?

3      **A.**     Due process, but also internal Justice Department. We  
4      can't confirm an investigation.

5 Q. So, if a distributor asked one of your agents should we  
6 be worried about this pharmacy we're supplying and you were  
7 conducting an investigation of that pharmacy let's say for  
8 something horrible like exchanging drugs for sex, that would  
9 not be disclosed to the distributor, correct, under this  
10 policy you've referenced?

11       **A.**     We would have to seek guidance from the U. S. Attorney  
12                  or the Department of Justice.

13 Q. Absent getting that guidance, you would not share that  
14 information, correct?

**A.** That's -- that's correct.

16 Q. And you understand that DEA investigations of doctors  
17 and pharmacies can, in some instances, take years and years  
18 and years?

**A.** That's correct.

20 Q. And the time you mentioned in your examination, the one  
21 time you mentioned where you learned that one of your agents  
22 was doing that, was sharing a list of, hey, watch out for  
23 these pharmacies, you told that agency to stop that,  
24 correct?

**A.** Well, didn't say watch out for these pharmacies.

1       That's not what was in the e-mail. The e-mail basically  
2 listed pharmacies and said these pharmacies were cut off by  
3 another distributor.

4       **Q.**     The one time that happened you told that agent to stop,  
5 correct? You stopped that practice, correct?

6       **A.**     That's correct.

7       **Q.**     It was commonplace for distributors like McKesson, and  
8 ABDC, and Cardinal to come in and give briefings to the DEA,  
9 correct, about their programs?

10      **A.**     I don't know if it's commonplace, but I know they come  
11 in.

12      **Q.**     Well, let me ask it this way. Is it true that  
13 registrants come in and give briefings to the DEA all the  
14 time?

15      **A.**     Registrants.

16      **Q.**     Okay. And that has included occasions where the  
17 defendants in this case come in and give briefings, correct?

18      **A.**     Yes. Defendants have been at the headquarters, yes.

19      **Q.**     We talked about some of the presentations in 2008.  
20 After that point in time, you're aware that distributors  
21 continued to ask for guidance from DEA?

22      **A.**     I was aware later on that they did, but it was through  
23 liaison policy, which is normal. That's what normally  
24 happens.

25      **Q.**     For example, you know that in June of 2011,

1 distributors sent DEA a letter asking for guidance on  
2 suspicious order monitoring and reporting through their  
3 Trade Association?

4 | A. Yes.

5 Q. And DEA did not answer that letter, correct?

6       **A.**    That's correct. We were directed not to answer that  
7 letter.

8 Q. Distributors sent another letter asking for guidance  
9 two years later, in July of 2013, regarding things like  
10 diligence and suspicious order reporting through their Trade  
11 Association, correct?

**A.** That's correct.

13 Q. And, again, they actually did that in connection with a  
14 planned meeting with DEA, correct?

15       **A.**     I don't know about that, but they did send that letter  
16           and, again, we were directed not to answer that letter.

17 Q. Are you aware that the DEA cancelled the meeting and  
18 ignored the letter?

19       **A.**     Well, we were directed not to answer the letter and I'm  
20           sure the meeting was cancelled. If there was a meeting,  
21           then I'm sure it was cancelled.

22 Q. Do registrants have a right to expect responses to  
23 written, electronic or telephonic requests from the DEA?

24 MR. ACKERMAN: Objection.

25 THE COURT: What's the objection?

1                   MR. ACKERMAN: Foundation, argumentative, outside  
2 the scope.

3                   MR. SCHMIDT: One of the road map stops was  
4 guidance, Your Honor, and I'm -- I'll lay a foundation.

5                   MR. ACKERMAN: But the question wasn't about DEA's  
6 guidance. It was about whether respondents have -- about  
7 respondents' expectations.

8                   THE COURT: Yes. The question was do registrants  
9 have a right to expect a response. You have to lay a  
10 foundation for that one, Mr. Schmidt.

11                  BY MR. SCHMIDT:

12                 **Q.** Do you understand that the DEA believed that DEA  
13 registrants have a right to expect responses to written  
14 electronic or telephonic requests?

15                 **A.** DEA registrants, yes, they have a right, but not  
16 advocacy groups.

17                 **Q.** Do you have an understanding that DEA registrants have  
18 a right to expect guidance regarding the CSA and its  
19 regulations?

20                 **A.** Yes, but again, the individual registrants can come in  
21 and request that guidance. The advocacy group doesn't  
22 really represent all of the distributors.

23                 **Q.** You're aware that government watchdogs made findings  
24 that DEA should give more guidance to distributors while you  
25 were at DEA, correct?

1           **A.**     Yes.

2                            MR. SCHMIDT: May I approach, Your Honor?

3                            THE COURT: Yes.

4                            BY MR. SCHMIDT:

5           **Q.**     I've given you a report from the GAO, June, 2015. More  
6                            DEA Information About Registrants' Controlled Substances  
7                            Roles Could Improve Their Understanding and Help Ensure  
8                            Access, DEF-WV-2181. This report came out on your watch,  
9                            correct?

10          **A.**     Yes.

11          **Q.**     And you're aware of this report, correct?

12          **A.**     Yes. I wrote the response to it.

13          **Q.**     And I was just going to point that out. If we look at  
14                            Page 82, you actually wrote a response to a draft of it,  
15                            correct?

16          **A.**     Yes.

17          **Q.**     Let's go to Page 82, please. I'm sorry, page 89. And  
18                            there we see your response, correct?

19          **A.**     Yes.

20          **Q.**     All right. Let's look at Page 34 of this report. And  
21                            I'm using the number in the lower left corner again. This  
22                            is shortly before you left DEA, correct?

23          **A.**     Yeah. About three or four months before.

24          **Q.**     They state a guidance document for distributors -- I'm  
25                            looking in the first full paragraph. A guidance document

1 for distributors similar to the one offered for pharmacies  
2 and practitioners could help distributors further understand  
3 and meet their roles and responsibilities under the CSA for  
4 preventing diversion, though the document may not need to be  
5 as detailed. Did I read that correctly?

6 **A.** Yes.

7 **Q.** Were you aware of that finding?

8 **A.** When I read that, yes, I was.

9 **Q.** Okay. If we skip a sentence, they give an example.  
10 They say DEA could -- it's actually two lines up and I  
11 didn't skip a sentence. I started halfway through the  
12 sentence because there's a comma where it looks like there  
13 would be a period or something. DEA could, for example,  
14 provide guidance around best practices in developing  
15 suspicious order monitoring systems. Were you aware of that  
16 finding?

17 **A.** Yes.

18 **Q.** DEA could also enhance its proactive communications  
19 with distributors. And then they give some examples. Do  
20 you see that?

21 **A.** Yes.

22 **Q.** And then let's skip to the next sentence. Such steps  
23 are key to addressing distributors' concerns, as without  
24 sufficient guidances and communication from DEA,  
25 distributors may not be fully understanding or meeting their

1       roles and responsibilities under the CSA for preventing  
2 diversion. Do you see that?

3       **A.**     Can I read that one more time?

4       **Q.**     Of course.

5       **A.**     Thank you.

6              Yes. I see that.

7       **Q.**     And then they say, additionally, in the absence of  
8 clear guidance from DEA, our survey data show that many  
9 distributors are setting thresholds on the amount of certain  
10 controlled substances that can be ordered by the customers,  
11 i.e., pharmacies and practitioners, which can negatively  
12 impact pharmacies and ultimately patients' access. Do you  
13 see that?

14      **A.**     Yes.

15      **Q.**     Do you agree with the idea that if thresholds are set  
16 too low they can negatively impact pharmacies and ultimately  
17 patient access?

18      **A.**     Well, I -- I can't agree or disagree because I don't  
19 know how you're setting the threshold and I don't know the  
20 customer. I don't know where the customer sits. So, no, I  
21 can't agree or disagree.

22      **Q.**     Fair. Let's go to their recommendations on Page 51.  
23              Do you see that they have three recommendations for  
24 executive action? The second is solicit input from  
25 distributors or associations representing distributors.

1           That would be a group like HDMA, correct?

2       **A.**   Had, yes.

3       **Q.**   What you referred to as an advocacy organization?

4       **A.**   That's what it is.

5       **Q.**   And develop additional guidance for distributors,  
6           regarding their roles and responsibilities for suspicious  
7           orders monitoring and reporting. Do you see that?

8       **A.**   Yes.

9       **Q.**   I take it -- well, let me -- let me ask you one more  
10          question.

11                   MR. SCHMIDT: May I approach, Your Honor?

12                   THE COURT: Yes.

13                   BY MR. SCHMIDT:

14       **Q.**   Mr. Rannazzisi, I've put in front of you MCWV-2208. Do  
15          you see that? It's dated December 20th, 2016, U. S.  
16          Department of Justice. And if you look at the Bates number  
17          in the bottom corner, you can see that this was provided to  
18          us by the DEA. Do you see this document?

19       **A.**   Yes.

20                   MR. SCHMIDT: I'd move this into evidence, Your  
21          Honor.

22                   THE COURT: Any objection?

23                   THE WITNESS: No. Have I seen this document?

24                   MR. SCHMIDT: No. I said do you see this  
25          document?

1                   THE WITNESS: Oh, do I see it? Okay.

2                   MR. SCHMIDT: I'm about to ask you that question  
3 but, first, I want to move it into evidence.

4                   MR. ACKERMAN: I don't think he's laid the  
5 foundation because the only question was do you see this  
6 document.

7                   MR. SCHMIDT: It's a U. S. Department of Justice  
8 letter to the Government Accountability Office produced by  
9 the DEA in this litigation. I think it's a government  
10 record.

11                  THE COURT: Mr. Farrell?

12                  MR. FARRELL: Yeah. I don't believe this is --  
13 I'm not saying he can't get the foundation to it, but I  
14 don't think he's laid it.

15                  MR. SCHMIDT: I'm trying to -- I'm trying to  
16 short-circuit, but let me see if I can help.

17                  BY MR. SCHMIDT:

18                  **Q.** Do you see it relates to in the subject line Re: DEA  
19 Status Reports? And then it references that GAO Report you  
20 were just looking at. Do you see that?

21                  **A.** Yes.

22                  **Q.** And do you see it's written to the Director of  
23 Healthcare and the Government Accountability Office, the  
24 Office of the Government that wrote that report we were just  
25 looking at?

1       **A.**     Yes.

2       **Q.**     And do you see in the first line it says the Drug  
3              Enforcement Administration provides the following status  
4              reports on actions taken to address the GAO Report? Do you  
5              see that?

6       **A.**     Yes.

7              MR. ACKERMAN: Your Honor --

8              MR. SCHMIDT: We'd move it in as a government  
9              record, Your Honor.

10             MR. ACKERMAN: So, Your Honor, this is after his  
11             tenure at the DEA. There's no -- Mr. Rannazzisi hasn't  
12             testified to anything other than the contents of a document  
13             that counsel hasn't established he saw before sitting on the  
14             stand today. All that he testified to was that the document  
15             says what's on its face.

16             MR. SCHMIDT: And, Your Honor, what I think is  
17             appropriate is for me to be able to move this in as a  
18             business record, as a government record, and then I will ask  
19             Mr. Rannazzisi if he's seen it. If he hasn't, I'll move on,  
20             but I think it's important to --

21             THE COURT: Have you laid the basis for it as a  
22             government record as an exception to the hearsay rule?

23             MR. SCHMIDT: I believe we have, Your Honor.  
24             Under Rule 806 -- I'm sorry. Under Rule 803 --

25             MR. FARRELL: Judge, to save you some time, our

1 objection is premised upon maintaining the scope of Mr.  
2 Rannazzisi as a fact witness and if the defendants believe  
3 that documents produced by the DEA are self-authenticating  
4 and admissible, we agree, and note that there are many such  
5 attached to the Prevosnik deposition.

6 MR. SCHMIDT: Your Honor, I have not looked at  
7 those documents. I move this document in. And I'm moving  
8 it in under 803 --

9 THE COURT: (8).

10 MR. SCHMIDT: 803(8), yes. Thank you. It sets  
11 out the Office's activities. It sets out a matter observed  
12 while under a legal duty to report. And it's factual  
13 findings from a legally authorized investigation insofar as  
14 this is the DEA responding to a GAO investigation with their  
15 update on steps taken as a result of that. It's all three  
16 clauses.

17 MR. ACKERMAN: The problem here, Your Honor, is  
18 that that's Mr. Schmidt's testimony. There's no testimony  
19 from a witness as to -- as to what this is. So, it's  
20 different from the documents that Mr. Rannazzisi saw during  
21 his tenure at the DEA and can testify to. There's not a --  
22 there's not a foundation from a witness.

23 MR. SCHMIDT: And I'll note, too, I believe the  
24 plaintiffs have given us designations for DEA witnesses and  
25 includes this as an exhibit. So, I think we can stipulate

1           that it comes in. You want it for Mr. Strait (phonetic).  
2           We want it for -- for the record. And then, I'll ask Mr.  
3           Rannazzisi if he knows about it. If he doesn't, I'll move  
4           on.

5           MR. ACKERMAN: I'm looking at the people who know  
6           more about this than I do.

7           THE COURT: I'm going to sustain the objection to  
8           this one on the basis of a lack of proper foundation through  
9           this witness.

10          MR. SCHMIDT: May I just ask him if he's seen it  
11          before?

12          THE COURT: You can use it to ask him some  
13          questions and --

14          MR. SCHMIDT: Okay.

15          BY MR. SCHMIDT:

16          Q. Let's go to the second page. Do you see it repeats the  
17          finding at the top regarding soliciting input from  
18          distributors or associations representing distributors, that  
19          language we looked at?

20          MR. ACKERMAN: Your Honor, it's your discretion,  
21          but I'd note that the document is still on the screen as if  
22          it's been admitted. Now it's not.

23          THE COURT: It's been removed. Okay.

24          MR. SCHMIDT: It's gone.

25          BY MR. SCHMIDT:

1       **Q.**    Do you see that finding we talked about?

2                  MR. FARRELL: Objection, Your Honor. I don't know  
3 that he's identified that the witness has seen this  
4 document, let alone seen Page 2.

5                  MR. SCHMIDT: I'm trying to move it in. Your  
6 Honor just said I could ask him -- use it as a basis to  
7 cross-examine and --

8                  THE COURT: Well, yeah. You can use it as a basis  
9 to ask him questions --

10                 MR. SCHMIDT: Okay.

11                 BY MR. SCHMIDT:

12       **Q.**    Do you see that finding --

13                 THE COURT: -- for cross examination.

14                 BY MR. SCHMIDT:

15       **Q.**    Do you see that finding we've just discussed, sir?

16       **A.**    On number 2?

17       **Q.**    Yes, at the top of Page 2?

18       **A.**    Okay.

19       **Q.**    And then, if you look at the second paragraph, do you  
20 see it says the GAO survey was conducted in 2015, prior to  
21 new DEA leadership, including a new acting administrator and  
22 new management for the Diversion Control Division.

23                 MR. FARRELL: Objection, Your Honor.

24                 THE COURT: Mr. Farrell?

25                 MR. FARRELL: He's simply reading it into the

1 record now rather than asking him questions.

2 THE COURT: Sustained.

3 MR. SCHMIDT: My question was simply going to be  
4 did he know about it and --

5 THE COURT: Well, you can ask him the question,  
6 but don't --

7 BY MR. SCHMIDT:

8 **Q.** Did you know about that finding?

9 **A.** No, I did not.

10 **Q.** Do you know about Congressional testimony Chuck  
11 Rosenberg gave before Congress after you left about the DEA  
12 being opaque when providing guidance to distributors?

13 **A.** I heard that before, yes.

14 **Q.** Are you aware that he said "I think we've been slow. I  
15 think we've been opaque. I think we haven't responded to  
16 them"?

17 **A.** I'm aware of that. I don't know where he got that  
18 information from. He never received a briefing from me  
19 before I left.

20 **Q.** Last topic, quotas. DEA sets quotas for controlled  
21 substances each year, correct?

22 **A.** Yes.

23 **Q.** But based on the estimated medical scientific research  
24 and industrial needs of the United States, correct?

25 **A.** That's correct.

1       **Q.**   And they're designed to set an exact quantity that will  
2       meet the legitimate medical demands, yet won't be more than  
3       necessary that could be removed to the illicit marketplace,  
4       correct?

5       **A.**   It's an estimate. It's not an exact quantity.

6       **Q.**   But that's the estimate, correct?

7       **A.**   That's the estimate.

8       **Q.**   And distributors can only ship pills that manufacturers  
9       make within the quota, correct?

10      **A.**   That's correct.

11      **Q.**   You said you oversaw the aggregate production quota,  
12       the APQ, correct?

13      **A.**   Yes. My staff did that.

14      **Q.**   And I just want to go back to that earlier OIG Report.

15      **A.**   Yes.

16      **Q.**   DEF-WV-1597. And the reason I'm going to this is  
17       because it has a helpful chart that shows quota changes over  
18       time. It's at Page 19 of the document, please.

19      **A.**   Yes.

20      **Q.**   And are you generally familiar with the quota changes  
21       that happened at least on your watch between, according to  
22       this, 2015 and 2005? I probably did a terrible job at  
23       drawing those lines. I put my 2015 a little farther over.  
24       But are you generally familiar with those quota increases?

25      **A.**   Yes.

1           **Q.**    During your tenure?

2           **A.**    Yes.

3           **Q.**    And they had -- to be fair to you, they had started  
4           increasing before your tenure, going all the way back into  
5           the late 90s, correct?

6           **A.**    Yes.

7           **Q.**    And they continued to increase during your tenure,  
8           correct?

9           **A.**    Uh-huh, yes.

10          **Q.**    And am I correct in understanding from your testimony  
11           yesterday that you believe that those increases were driven  
12           by good faith prescribing practices?

13          **A.**    I think my testimony was prescribing practices and then  
14           research and development, export, and the other things, yes.

15          **Q.**    Okay. And the prescribing practices portion of that  
16           was driven by legitimate medical need, correct?

17          **A.**    Well, legitimate medical need and then, of course,  
18           doctors that are prescribing illegally.

19          **Q.**    Okay. You said yesterday you took diversion into  
20           account though in setting the quota, correct?

21          **A.**    We looked at that over the years, yes.

22          **Q.**    And you had the concern that if you arbitrarily cut the  
23           level of the quota, that could have negative consequences  
24           for real-life patients, correct?

25          **A.**    Yes, that's correct.

1           **Q.**   Now --

2                 THE COURT: If you're at a stopping place, Mr.  
3 Schmidt, we need to take a break.

4                 MR. SCHMIDT: Okay. Why don't we take a break,  
5 Your Honor.

6                 THE COURT: Is this is a good place?

7                 MR. SCHMIDT: Yes, sir.

8                 THE COURT: All right. Let's be in recess for  
9 about ten minutes.

10               (Recess taken)

11               (Proceedings resumed at 3:40 p.m. as follows:)

12               THE COURT: Mr. Schmidt.

13               MR. SCHMIDT: Thank you.

14 BY MR. SCHMIDT:

15           **Q.**   Mr. Rannazzisi, I have one final topic that I hope  
16 is brief that I have to cover in light of some of the  
17 opinions you've given. You gave some pretty strong  
18 opinions about the distributors in this case. Correct?  
19 You offered -- let me re-ask. You offered some pretty  
20 strong views on the distributors in this case; correct?

21           **A.**   I offered views on distributors, yes.

22           **Q.**   You've also offered strong views in your work on  
23 doctors in terms of blaming doctors; correct?

24           **A.**   I've discussed doctors and what their role is, yes.

25           **Q.**   For example, just a few weeks ago you recorded on a

1           television showing saying the opioid crisis started with  
2 prescriptions, prescriptions and patient care, this idea  
3 that we weren't adequately treating pain. Correct?

4         **A.**    Which show was that?

5         **Q.**    It was the HBO show.

6         **A.**    I don't have a transcript, but I seem to remember  
7 saying something about doctors during that time.

8         **Q.**    Do you believe that the opioid crisis started with  
9 prescriptions?

10         **A.**    I believe the opioid crisis -- the prescriptions had a  
11 lot to do with the opioid crisis, yes.

12         **Q.**    Do you believe it started with prescriptions?

13         **A.**    I would say that prescriptions -- yes, I'd say that.

14                 MR. SINGER: Objection, move to strike, Your  
15 Honor. I think Mr. Schmidt, after objecting to expert  
16 opinions from this witness, is now seeking just that.

17                 THE COURT: Well, I don't think that's an expert  
18 opinion. That's a lay opinion based on his experience,  
19 isn't it, Mr. Schmidt?

20                 MR. SCHMIDT: I think so, Your Honor.

21                 THE COURT: I'll overrule the objection.

22 BY MR. SCHMIDT:

23         **Q.**    You've taken issue with manufacturers in your work;  
24 correct?

25         **A.**    Yes.

1 Q. You've taken issue with chain pharmacies in your work;  
2 correct?

3           **A.**       Yes.

4 Q. You blamed independent pharmacies; correct?

5           **A.**       Yes.

6 Q. In terms of you, you had ultimate authority of the  
7 Office of Diversion Control for 10 years during the opioid  
8 crisis; correct?

9           **A.**       Yes.

10 Q. There was an opioid crisis the entire time that you  
11 were the head of DEA's Office of Diversion Control; correct?

**A.** That's correct, yes.

13 Q. It worsened during your tenure; correct?

14           **A.**     It, it did increase, yes.

15 Q. Including here in West Virginia; correct?

16           **A.**       I -- yes.

Q. And you were the senior --

18      **A.**     Across the country.

19 Q. Yes. You were the senior most law enforcement official  
20 at DEA responsible for pharmaceutical diversion; correct?

**A.** That's correct, yes.

22 Q. And despite the issue you've taken with others, am I  
23 right that you take no responsibility for the opioid crisis?

1           **Q.**   Zero percent?

2           **A.**   Yes, zero percent.

3           **Q.**   In fact, I've had the chance to ask you questions about  
4           your fulfillment of these responsibilities, and you've told  
5           me when it comes to registration, with the powers available  
6           to you, you believe you were perfect?

7           **A.**   We did registration in line with what the law allowed  
8           us to do, yes.

9           **Q.**   Registration of doctors and pharmacies, given the  
10          powers you had, did you execute those powers perfectly?

11          **A.**   We executed them according to the law. So if we're  
12          dealing with the law, yes, we, we did it as far as the law  
13          would allow us to do.

14          **Q.**   Given the powers you had to investigate doctors and  
15          pharmacies, you exercised those perfectly. True?

16          **A.**   Yes, within the resources we had and within the law, we  
17          did, yes.

18          **Q.**   Given the powers you had regarding quotas, you believe  
19          you executed those powers perfectly; correct?

20          **A.**   Again, we were required to follow the statutes and the  
21          laws related to quota and we did so appropriately, yes.

22          **Q.**   You believe you did so perfectly given the powers you  
23          had regarding quotas?

24          **A.**   We did the best we could do within the confines of the  
25          law, yes.

1       **Q.**    Let's cull up July -- all right. Nevermind. And you  
2           think you gave perfect guidance to distributors; correct?

3       **A.**    We gave the distributors the guidance that we were able  
4           to give within the confines of the policies and procedures  
5           of both DEA and DOJ.

6       **Q.**    And you wouldn't do anything differently in terms of  
7           how you approached the opioid crisis while you were at the  
8           DEA; correct?

9       **A.**    I've thought about this because you asked that before.

10      **Q.**    Do you remember how you answered it before?

11      **A.**    I wasn't, I wasn't sure. I wasn't -- I don't remember  
12           how I answered it before, but I, I didn't have a lot of time  
13           to think about it.

14      **Q.**    Okay. Would you do things differently? Just "yes" or  
15           "no"?

16      **A.**    It's not a "yes" or "no" question.

17      **Q.**    I'll move on then. You left the DEA in 2015; is that  
18           right?

19      **A.**    Yes.

20      **Q.**    And, in your words, you retired because they  
21           transferred you to another area of the DEA and you felt it  
22           was time to leave; correct?

23      **A.**    Yes. They, they transferred me -- they basically said  
24           that I'll be in a position that will be named later so --

25      **Q.**    You went from supervising 300 people to supervising no

1 people; correct?

2 **A.** That's correct.

3 **Q.** And that wasn't a change you wanted; correct?

4 **A.** I accept the fact that the acting administrator -- you  
5 serve at the will of the administrator. And the acting  
6 administrator wanted to make a change, so I accepted that  
7 fact.

8 **Q.** It wasn't a change you requested, was it?

9 **A.** It wasn't a change that I requested, no.

10 **Q.** And instead of agreeing to hold a position where you  
11 supervised no people, you chose to retire; correct?

12 **A.** I decided that there was uncertainty with what was  
13 going to happen. I could have been transferred. I didn't  
14 want my family to get transferred another time. So I  
15 decided to stay -- to retire, yes.

16 **Q.** At the time you retired, or prior to the time you  
17 retired, the Office of the Inspector General opened an  
18 investigation of you regarding serious misconduct with the  
19 House of Representatives; correct?

20 **A.** They opened an investigation of me because the House of  
21 Representatives -- two, two representatives claimed that I  
22 tried to intimidate them.

23 **Q.** And you left the DEA without getting a letter from the  
24 Office of Inspector General exonerating you; correct?

25 **A.** I never received a letter.

1 Q. Since you've left, you now get a government pension;  
2 correct?

3       **A.**     I do have a government pension, yes.

4 Q. And your only other income comes from working with  
5 plaintiff lawyers; correct?

6           **A.**       Yes.

7 Q. And I think you said the other day, or maybe yesterday,  
8 that you've received \$860,000 for working with plaintiff  
9 lawyers in opioid litigation since you left the DEA;  
0 correct?

11 A. Yes, since 2017.

12 Q. And you testified that you weren't getting paid for  
13 your testimony here; correct?

**A.** Testimony or prep.

15 COURT REPORTER: I'm sorry?

16 THE WITNESS: Prep, testimony or preparation.

17 BY MR. SCHMIDT:

18 Q. But you have been paid money, a small portion of  
19 that \$860,000 from one of the law firms in this case;  
20 correct?

21      **A.** Yes, a very small portion.

22 Q. Small portion being \$7,000; correct?

23           **A.**       Yes.

24 MR. SCHMIDT: That's all I have, Your Honor.

25 THE COURT: Any other cross of Mr. Rannazzisi?

1                   MS. WICHT: Yes, Your Honor, there will be. Can I  
2 just have the Court's indulgence for a moment while we get  
3 set up here?

4                   THE COURT: Yes.

5                   MS. WICHT: Thank you.

6                   CROSS EXAMINATION

7 BY MS. WICHT:

8 **Q.** Good afternoon, Mr. Rannazzisi.

9 **A.** Good afternoon.

10 **Q.** My name is Jennifer Wicht and I represent Cardinal  
11 Health. I am going to be doing my best to not duplicate any  
12 of the questions, or many of the questions you've already  
13 answered so far. And as a result, it may seem that I'm  
14 jumping around a little bit among topics. So I apologize  
15 for that and I hope you can follow me.

16                  So I want to start, Mr. Rannazzisi, by following up  
17 on -- just a little bit on the questions that you addressed  
18 both with Ms. Singer and with Mr. Schmidt and you testified  
19 about pain clinics. Do you recall generally testifying  
20 about that topic?

21 **A.** Yes.

22 **Q.** Okay. And I, I believe the testimony that you've  
23 already given is that there are pain clinics that are  
24 legitimate -- engaged in the legitimate practice of  
25 medicine; correct?

1       **A.**    That's correct.

2       **Q.**    And there are also prescribers who specialize in the  
3           treatment of pain; correct?

4       **A.**    That's correct.

5       **Q.**    And the same thing that's true of pain clinics is true  
6           of prescribers who specialize in the practice of pain; that  
7           is, there are prescribers who specialize in the practice of  
8           pain who are engaged in the legitimate practice of medicine.  
9           Correct?

10      **A.**    That's correct.

11      **Q.**    So not -- just because a doctor is a pain specialist  
12           doesn't mean that they're prescribing in any sort of a rogue  
13           fashion; correct?

14      **A.**    Could you repeat that, please?

15      **Q.**    Sure. Just because a physician is a pain specialist,  
16           that doesn't mean that they're prescribing in any sort of a  
17           rogue fashion?

18      **A.**    That's correct. In the alternative, a pain specialist  
19           can prescribe in a rogue fashion as well.

20      **Q.**    But not all of them are?

21      **A.**    That's correct, not all of them.

22      **Q.**    Okay. I want to just go back for a moment to the  
23           definition of suspicious orders in the Code of Federal  
24           Regulations. And I think we have our own version of it that  
25           I'll put up on the screen which I think is slide 3, but

1 you've looked at it with both Ms. Singer and Mr. Schmidt.

2 I actually had the wrong slide. I apologize. Can we  
3 try 2? There we go.

4 And this -- you recognize that as the Code of Federal  
5 Regulations' definition of a suspicious order; correct?

6 **A.** Yes.

7 **Q.** And the Code of Federal Regulations is what provides  
8 the legal definition of a suspicious order; correct?

9 **A.** Yes.

10 **Q.** And that's DEA's official definition of a suspicious  
11 order as well; right?

12 **A.** The DEA follows the Code of Federal Regulations, yes.

13 **Q.** And there's no other definition that you're aware of of  
14 a suspicious order; correct?

15 **A.** Just the Code of Federal Regulations' definition.

16 **Q.** Now, the definition includes some terms we've already  
17 talked about; orders of unusual size, orders deviating  
18 substantially from a normal pattern, and orders of unusual  
19 frequency. Correct? Those are the components of the  
20 definition of a suspicious order under the regs?

21 **A.** Yes.

22 **Q.** And the regs don't -- the regulations do not further  
23 define the term "unusual size;" correct?

24 **A.** That's correct.

25 **Q.** Nor do they offer a further definition of "unusual

1 frequency;" right?

2 **A.** That's correct.

3 **Q.** And they don't define what it means to deviate  
4 substantially from a normal pattern; correct?

5 **A.** That is correct.

6 **Q.** And the regulation doesn't quantify what the line is  
7 between usual and unusual; right?

8 **A.** That is correct also.

9 **Q.** And, now, when you were at DEA -- and I'll talk about  
10 your time between 2005 and 2015 that we've generally been  
11 focused on -- if a registrant asked you what a suspicious  
12 order was, you would tell them it's an order of unusual  
13 size, frequency, or substantially deviating from a normal  
14 ordering pattern; correct?

15 **A.** We would refer them to the regs. And if they had a  
16 specific question, then depending on who they were talking  
17 to, if it was liaison policy, I'm sure the liaison policy  
18 would have given them some type of guidance if it's specific  
19 to, specific set of facts.

20 **Q.** You would have referred the registrant to the  
21 definition in the, in the regulation; correct?

22 **A.** Unless they had some specific set of facts that they  
23 were looking for, yes.

24 **Q.** And if a registrant had a specific set of facts about  
25 an order, would the DEA tell them that's an order of unusual

1 size or pattern or frequency?

2       **A.** No. I'm talking about a specific set of facts as far  
3 as -- for instance, if they'd say, "What if I have a  
4 customer that's ordering an over-abundance of a certain type  
5 of drug?" And then I believe that they might say, "Well,  
6 what's the drug?" And they might say, "Well, we would  
7 consider this in the category of substantially deviating,"  
8 say. So they might -- further explain. And then actually  
9 the letter, the December, 2007 letter further explained  
10 those as well.

11      **Q.** During your tenure, sir, isn't it correct that DEA took  
12 the position that it would not tell a registrant whether a  
13 particular order was a suspicious order under the definition  
14 of the regs?

15      **A.** That's correct. We would not be specific -- we would  
16 not tell a registrant, "This is, this is suspicious, don't  
17 ship it." We wouldn't say that.

18      **Q.** And it's true, is it not, that in your view there are  
19 lots of different ways that you could define unusual size;  
20 right?

21      **A.** Yes.

22      **Q.** It could mean unusual in comparison to that particular  
23 pharmacy's past ordering practices; right?

24      **A.** That's correct.

25      **Q.** It could mean unusual when compared to the ordering

1 practices of other pharmacies in the area; correct?

2 **A.** That's also correct.

3 **Q.** And there could be other factors that would bear on  
4 whether an order was of unusual size as well; correct?

5 **A.** Yes.

6 **Q.** And, now, the word "unusual" also applies to the  
7 consideration of order frequency under the regulations;  
8 correct?

9 **A.** Yes.

10 **Q.** And those various definitions or ways of determining  
11 whether an order is unusual are not spelled out in the  
12 regulations; correct?

13 **A.** No.

14 **Q.** And let me -- you, you testified about the possibility  
15 that if a registrant called, your staff might provide  
16 guidance or input to the registrants on a particular  
17 situation they had.

18 So let me just ask you this. You're not aware, are  
19 you, Mr. Rannazzisi, of any specific guidance that your  
20 staff offered to a registrant; correct?

21 **A.** No. However, that's -- the December letter provided a  
22 little more specific guidance on what an unusual -- what to  
23 look for on unusual size, frequency, deviating substantially  
24 from the normal ordering pattern.

25 **Q.** Since you mentioned the December of 2007 letter, let me

1 just ask -- that was the last guidance letter that your  
2 office sent to registrants, correct, during your tenure at  
3 DEA?

4 **A.** Yes.

5 **Q.** There were no additional letters sent after that  
6 providing guidance?

7 **A.** I don't recall any additional letters.

8 **Q.** You've testified, Mr. Rannazzisi, on direct examination  
9 about -- that distributors in their Suspicious Order  
10 Monitoring Systems could use dispensing data from their  
11 pharmacy customers. Do you recall that?

12 **A.** Yes.

13 **Q.** And, and that's a subject that you've offered opinions  
14 about in a, in a different opioid case, correct, dispensing  
15 data and suspicious order monitoring?

16 **A.** I don't recall if I discussed that in the MDL  
17 deposition or another case. I know I discussed it. I just  
18 don't remember which case I discussed it in.

19 **Q.** Okay. No problem. And I want to be -- I really was  
20 only saying that to say that I want to be clear. I'm not  
21 asking for any opinions that you may have offered somewhere  
22 else.

23 **A.** Okay.

24 **Q.** What I want to ask you is while you were at the DEA,  
25 Mr. Rannazzisi, you never told distributors that they must

1 or should be collecting dispensing data from their pharmacy  
2 customers and incorporating it into their Suspicious Order  
3 Monitoring Systems; correct?

4 **A.** I never told anybody --

5 **Q.** And --

6 **A.** -- that.

7 **Q.** And --

8 **A.** But that doesn't -- you know, that doesn't include the  
9 staff. That was one of the things that I'm sure they  
10 discussed with the distributors.

11 **Q.** You're not aware of any instance in which staff  
12 discussed that with any distributor; correct?

13 **A.** I can't give you a specific instance, but I knew staff  
14 knew the dispensing data was important.

15 **Q.** And while you were at the DEA, DEA, to your knowledge,  
16 never issued any written guidance telling distributors that  
17 they must or should collect dispensing data from customers;  
18 correct?

19 **A.** I never said they should collect. I've said during due  
20 diligence they should review it if they can't resolve the  
21 reason for the, for the anomalies and ordering patterns. So  
22 we suggest it's part of the due diligence process.

23 **Q.** Well, let's be clear, though. You've testified that  
24 you never -- you don't recall ever saying that to any  
25 distributor though; correct?

1       **A.**   I never said it.

2       **Q.**   And you're not aware of staff saying that to any  
3 distributor; correct?

4       **A.**   I can't give you an instance where staff has said that.

5       **Q.**   I'm going to ask you some questions specific to  
6 Cardinal Health, Mr. Rannazzisi.

7              Yesterday Ms. Singer refreshed your recollection with  
8 an affidavit that you signed in the Cardinal Health, 2012  
9 Cardinal Health action. Do you remember that?

10      **A.**   Yes. It was a declaration in lieu of testimony.

11      **Q.**   Okay. And after she showed you that declaration, you  
12 testified that DEA conducted an audit of Cardinal Health's  
13 Peabody, Massachusetts distribution center; and that during  
14 that audit, Cardinal Health was given guidance by DEA on due  
15 diligence for chain drug stores. Do you recall that?

16      **A.**   Yes.

17      **Q.**   I just have a few questions about that, Mr. Rannazzisi.  
18 To be clear, you did not conduct that audit of Cardinal  
19 Health's Peabody distribution center; correct?

20      **A.**   No. I believe it was Inspector Mike Arpaio that was  
21 the lead auditor in that.

22      **Q.**   And he conducted that audit --

23      **A.**   Yes.

24      **Q.**   -- of Cardinal Health? So everything that you know  
25 about that meeting between DEA and Cardinal Health at that

1 audit you learned from Mr. Arpaio; correct?

2 **A.** Yes.

3 **Q.** And that includes anything that Mr. Arpaio might have  
4 said to Cardinal Health, correct?

5 **A.** Yes.

6 **Q.** And anything that Cardinal Health employees said to  
7 Mr. Arpaio; correct?

8 **A.** That's correct.

9 **Q.** You were shown a copy yesterday of a memo memorializing  
10 the internet pharmacy briefing that certain DEA officials  
11 conducted with Cardinal Health. Do you recall that?

12 **A.** Yes.

13 **Q.** And we can pull that up. It's P-9114.

14 Do you have that in front of you still, Mr. Rannazzisi?

15 **A.** I'm not even looking for it. It's on the screen.

16 **Q.** Okay. It's on the screen. And the subject line of  
17 that memo states "Meeting with Cardinal Health, Inc.,  
18 Concerning Internet Pharmacies." Correct?

19 **A.** That's correct.

20 **Q.** And you testified that you didn't attend this meeting;  
21 right?

22 **A.** I did not attend this meeting.

23 **Q.** And the memo was prepared by Mr. Michael Mapes;  
24 correct?

25 **A.** That's correct.

1       **Q.**   And he did attend the meeting; correct?

2       **A.**   I believe he was the principal briefer, yes.

3       **Q.**   Along with Mr. Kyle Wright from the DEA?

4       **A.**   I can't see who's --

5       **Q.**   Yeah. If you look at the --

6       **A.**   That's what I'm looking at now.

7       **Q.**   You know what --

8       **A.**   Yeah. I don't believe Kyle Wright's in here.

9       **Q.**   Okay. Fair enough. And the, the, the way that you  
10      learned about the meeting, Mr. Rannazzisi, was from this  
11      memo and a briefing; correct?

12      **A.**   This memo came after I was briefed on the meeting.

13      **Q.**   And --

14      **A.**   I was briefed on the meeting after the meeting either  
15      that day or the next day. And then I would get the memo  
16      following.

17      **Q.**   And the memo that the DEA staff prepared after the  
18      meetings were to inform you about what was said at the  
19      meeting and what was talked about; correct?

20      **A.**   Actually, it was to memorialize the meeting.

21      **Q.**   To memorialize the meeting?

22      **A.**   Yes.

23      **Q.**   Okay. And you wanted those memos prepared; correct?

24      **A.**   Those memos would be prepared for any meetings we had,  
25      so, yes.

1       **Q.**   And I'm sure you expected your staff to make sure that  
2           the memos were complete, didn't you?

3       **A.**   Yes.

4       **Q.**   And, of course, the memos needed to be accurate;  
5           correct?

6       **A.**   Yes.

7       **Q.**   And these were important meetings and it was important  
8           to you to document what had been said to the distributors at  
9           the meeting; correct?

10      **A.**   Yes.

11      **Q.**   And if you thought that the staff would have conducted  
12           the meeting and you were missing some information that you  
13           thought should have been included, you probably would have  
14           added it in or asked them to include it; correct?

15      **A.**   If there was something missing that I knew was missing,  
16           I would ask them. But since I wasn't at the meeting, I  
17           relied on them to accurately report and memorialize the  
18           meeting.

19      **Q.**   So if you take a look at this memo, Mr. Rannazzisi, and  
20           it's just the one page that you see on the screen there, the  
21           memo doesn't contain any discussion of ingredient limit  
22           reports, does it?

23      **A.**   No, it doesn't.

24      **Q.**   It doesn't contain any discussion of excessive purchase  
25           reports, does it?

1       **A.**     No, it doesn't.

2       **Q.**     It doesn't contain any discussion of after-the-fact  
3              reports of shipments; correct?

4       **A.**     No, the memo doesn't contain any of that.

5       **Q.**     The memo doesn't reflect any discussion of -- the memo  
6              doesn't say that Cardinal Health was told that when they  
7              were recording a suspicious order, they were required to say  
8              why the order was suspicious; right?

9       **A.**     No, that's not in there either.

10      **Q.**     And the memo doesn't say that Cardinal Health was told  
11              that when they were reporting a suspicious order, they  
12              should provide information about the pharmacy; correct?

13      **A.**     No, that's not in there. But I do believe that some of  
14              that is -- would be attached in the PowerPoint presentation  
15              that was given.

16      **Q.**     Well, the PowerPoint presentation -- if you have the  
17              exhibit in front of you -- it should be there behind it, Mr.  
18              Rannazzisi. So I'll invite you to flip through it and let  
19              me know if you see something in the PowerPoint presentation  
20              that said when a suspicious order is reported, the  
21              distributor is required to say why the order is suspicious.

22      **A.**     Well, this was -- I don't know if that was in the  
23              PowerPoint or not, but some of the other things you asked  
24              me --

25      **Q.**     Well --

1       **A.** -- were definitely in the PowerPoint.

2       **Q.** Well, that's what I'm asking you about now. So you're  
3           saying -- your answer is that's not in the PowerPoint?

4       **A.** I don't have the PowerPoint in front of me, but I  
5           don't, I don't remember it being -- I don't recall it being  
6           in the PowerPoint. But I have a lot of paper in front of me  
7           so -- you don't happen to have it, do you?

8       **Q.** I believe I do. I can hand you another copy. I'm  
9           happy to. It's P-9114. Maybe I don't have it.

10                  MS. WICHT: I'm sorry, Your Honor. I'll check.

11                  May I approach, Your Honor?

12                  THE COURT: Yes.

13                  BY MS. WICHT:

14       **Q.** And the question that I've asked you, sir, is  
15           whether there's anywhere in that memo or PowerPoint  
16           presentation that indicates what information Cardinal  
17           Health was required to submit to DEA in a suspicious  
18           order report.

19       **A.** I don't, I don't see it in the PowerPoint.

20       **Q.** Now, the, the memo, Mr. Rannazzisi, also doesn't say  
21           anything about any obligation to document due diligence;  
22           correct?

23       **A.** No, it does not.

24       **Q.** Now, are you aware that Kyle Wright testified that he  
25           did not tell distributors in these internet pharmacy

1       briefings that there was an obligation to document due  
2       diligence?

3       **A.**     No, I was not aware of that. I don't know what Kyle  
4       Wright's testimony is.

5       **Q.**     I'm sorry. The last part?

6       **A.**     I don't know what Kyle Wright's testimony is.

7       **Q.**     But Kyle Wright --

8       **A.**     I don't even know if Kyle Wright was at this meeting.

9       **Q.**     But Kyle Wright in general was one of the presenters at  
10      the distributor initiative meetings; correct?

11      **A.**     Yeah. He was one of several, several people who  
12      attended these meetings.

13      **Q.**     And you were not; correct?

14      **A.**     No, I was not.

15      **Q.**     And are you aware that Mr. Mapes testified that if  
16      there had been anything else discussed in the meeting with  
17      Cardinal Health, he would have included it in his cover  
18      memo?

19      **A.**     Again, I didn't see Mr. Mapes' testimony, so I don't  
20      know.

21      **Q.**     But that would be consistent with your expectations for  
22      what was included in the memo; correct?

23      **A.**     I would expect that Mr. Mapes would do a complete memo  
24      including everything else in -- that happened during the  
25      meeting.

1 Q. Mr. Rannazzisi, do you know which Cardinal Health  
2 distribution center shipped medications to  
3 Cabell/Huntington, West Virginia.

4           **A.**       No, I don't.

5 Q. Are you aware that Cardinal Health has a distribution  
6 center in Wheeling, West Virginia?

**A.** No, I'm not aware of that.

8 Q. In your entire --

9 MR. ACKERMAN: One minute. I think I know where  
10 we're going. I'm going to preserve our scope objection with  
11 respect to questions regarding West Virginia because Mr.  
12 Rannazzisi was not questioned regarding West Virginia in his  
13 MDL deposition.

14 THE COURT: Okay.

15 MR. ACKERMAN: And that will be a standing  
16 objection. I don't want to interrupt.

17 BY MS. WICHT:

18 Q. Now, Mr. Rannazzisi, during your entire tenure at  
19 DEA, DEA never issued an Order to Show Cause against  
20 Cardinal Health's Wheeling, West Virginia distribution  
21 center: correct?

22       **A.**     I, I don't know, but during my -- I don't know if they  
23           ever received one or not. I think I would remember that,  
24           but I'm not sure.

25 Q. During the time that you were at the Office of

1       Diversion Control from 2005 to 2015, it's fair to say you  
2       would remember if you had issued an Order to Show Cause  
3       against Cardinal Health's Wheeling, West Virginia  
4       distribution center?

5       **A.**     I think I would remember, yes.

6       **Q.**     And you don't recall that; correct?

7       **A.**     I don't recall that.

8       **Q.**     And during the time that you were in the Office of  
9       Diversion Control at DEA, DEA never issued an Immediate  
10      Suspension Order against Cardinal Health's Wheeling, West  
11      Virginia distribution center; correct?

12      **A.**     I -- if they didn't get an Order to Show Cause served  
13      on them, they wouldn't have an ISO.

14      **Q.**     You discussed with Ms. Singer yesterday an enforcement  
15      action that was taken against other Cardinal Health  
16      distribution centers in late 2007. Do you recall that?

17      **A.**     Yes.

18      **Q.**     And that -- those enforcement actions issued against  
19      distribution centers other than Wheeling, West Virginia  
20      concerned distributions to what DEA contended were internet  
21      pharmacies; is that right?

22      **A.**     Yes. I'd have to go back and look at the Order to Show  
23      Cause but, yes, I believe that's correct.

24      **Q.**     All right. Now, at the time that DEA took action  
25      against Cardinal Health in 2007, your office had possession

1 of Cardinal Health's ARCos data going back years before  
2 2007; correct?

3 **A.** I would hope so. Cardinal Health was required under  
4 the Act to provide that ARCos data.

5 **Q.** And Cardinal Health did provide that ARCos data;  
6 correct?

7 **A.** Yes, I guess, yes.

8 **Q.** You don't have any recollection --

9 **A.** I don't have any recollection that they didn't, but  
10 they're required to under the Act under 827.

11 **Q.** And DEA used that ARCos data to identify shipments that  
12 DEA alleged were suspicious in the 2007 Orders to Show Cause  
13 and ISOs; correct?

14 **A.** Retrospectively, yes, because they were not -- we  
15 didn't have the suspicious orders.

16 **Q.** And enforcement action against Cardinal Health's  
17 Lakeland, Florida distribution center in 2012 raised  
18 allegations about Cardinal Health's distributions to four  
19 specific pharmacies in Florida. Do you recall that?

20 **A.** I, I think I said I don't have the document, but if you  
21 want me to look or if you have the Order to Show Cause  
22 document or --

23 **Q.** That's okay. I'll move on from the specifics if you  
24 don't recall and I'll just ask you this. At the time that  
25 DEA took action against Cardinal Health in 2012, again your

1 office had possession of Cardinal Health's ARCOS data going  
2 back years before that; correct?

3 **A.** Yes, we did. But, again, ARCOS, ARCOS data could only  
4 be looked at retrospectively, months after transactions  
5 occurred.

6 **Q.** And you used that ARCOS data to identify shipments that  
7 DEA alleged were suspicious in the context of the Lakeland,  
8 Florida Immediate Suspension Order; correct?

9 **A.** Yes, that is correct.

10 **Q.** And that ARCOS data that you used in 2007 and 2012 to  
11 form the basis of the allegations in the enforcement action  
12 also reflected every shipment of opioids by Cardinal Health  
13 to every pharmacy in West Virginia; correct?

14 **A.** Yes, it should.

15 **Q.** And, obviously, that would include every pharmacy in  
16 Cabell/Huntington; correct?

17 **A.** Again, it should, yes.

18 **Q.** Now, from the -- from 2012 until the time you left DEA  
19 in 2015, DEA continued to receive ARCOS data reflecting  
20 every shipment of every opioid by Cardinal Health to every  
21 pharmacy in Cabell/Huntington; correct?

22 **A.** Again, according to 827, that's a requirement, so, yes.

23 **Q.** And you're not aware of Cardinal Health ever failing to  
24 fulfill that requirement; correct?

25 **A.** I'm not aware of that.

1       **Q.** Now, during your tenure with the Office of Diversion  
2 Control from July, 2005 to October of 2015, you never  
3 instituted any enforcement proceedings against Cardinal  
4 Health based on any shipment made to Cabell/Huntington, West  
5 Virginia; correct?

6       **A.** I don't believe so.

7       **Q.** In your work at DEA, you never conducted any inspection  
8 of Cardinal Health's Suspicious Order Monitoring System;  
9 correct?

10      **A.** Me personally?

11      **Q.** You personally.

12      **A.** No.

13      **Q.** And you're familiar with a DEA employee name Kyle  
14 Wright; correct? You've mentioned him a few times already.

15      **A.** Yes.

16      **Q.** He -- Mr. Wright reported to you?

17      **A.** He reported to his section chief who ultimately  
18 reported to me, yes.

19      **Q.** Are you aware that Mr. Wright regularly communicated  
20 with Cardinal Health between 2005 and 2007 about Cardinal  
21 Health's efforts to address DEA's concerns about internet  
22 pharmacies?

23      **A.** Well, he was in a section that would talk to not just  
24 Cardinal Health, but other types of registrants.

25      **Q.** So you, you would expect him to have been talking to

1           Cardinal Health on that subject in that time frame; right?

2       **A.**    I expected him to talk to a number of registrants, yes.

3       **Q.**    Including Cardinal Health?

4       **A.**    Yes.

5       **Q.**    And are you aware that on April 26th, 2007, Kyle Wright  
6           spoke with two of the Cardinal Health employees in charge of  
7           anti-diversion and told them that he thought they were,  
8           quote, doing the right things and heading in the right  
9           direction?

10      **A.**    I don't recall that specific -- I don't recall that,  
11           no. Do you have the document or --

12      **Q.**    I was just asking if you were aware of it, sir.

13      **A.**    No, I don't believe I was aware of that.

14      **Q.**    Now, you mentioned on your direct examination with Ms.  
15           Singer someone named Barbara Boockholdt --

16      **A.**    Boockholdt.

17      **Q.**    I'm sorry -- who worked with you at DEA?

18      **A.**    Yes.

19      **Q.**    And she was the chief of the regulatory section at DEA  
20           headquarters; is that correct?

21      **A.**    Chief regulatory investigations, yes.

22      **Q.**    And are you -- you're aware, are you not, that in 2009  
23           DEA officials conducted a week-long visit at Cardinal  
24           Health's headquarters in Ohio meeting with Mr. Michael Mone  
25           and others to review Cardinal Health's improvements to its

1 Suspicious Order Monitoring System?

2 **A.** I recall that there was a team that went to Cardinal.

3 I don't recall who exactly was on that team or when it  
4 happened. But, yeah, I recall there was a meeting.

5 **Q.** And are you aware that Ms. Barbara Boockholdt attended  
6 that meeting from DEA headquarters?

7 **A.** If it was a regulatory meeting, there's a good  
8 possibility that she would have attended that meeting.

9 **Q.** But you did not attend the meeting; correct?

10 **A.** I did not attend that meeting.

11 **Q.** So you don't know what DEA said to Cardinal Health  
12 about Cardinal Health's Suspicious Order Monitoring System  
13 in that meeting; correct?

14 **A.** I do not.

15 **Q.** After you left DEA, are you aware of the fact that  
16 there were meetings between Mr. Todd Cameron, the head of  
17 Anti-Diversion at Cardinal Health, and officials at DEA  
18 headquarters to talk about Cardinal Health's Suspicious  
19 Order Monitoring System?

20 **A.** It would be after I left, so, no.

21 **Q.** You're not aware of those -- how many meetings  
22 occurred?

23 **A.** No.

24 **Q.** Obviously, you didn't attend?

25 **A.** Not after I left, no.

1       **Q.**   Before you left DEA, had you invited Mr. Cameron in to,  
2                          to DEA to discuss Cardinal Health's system?

3       **A.**   I never invited Todd Cameron -- is it Todd Cameron?  
4                          Yeah. No.

5       **Q.**   So do you have -- so you never received -- it's fair to  
6                          say you never received any information or briefing on  
7                          Cardinal Health's Suspicious Order Monitoring System post  
8                          2012; correct?

9       **A.**   The last briefing I received was before I was going to  
10                         testify in the TRO hearing in Washington, D.C.

11       **Q.**   And that would have been in 2012 sometime?

12       **A.**   That would have been, yeah, probably February --  
13                         February of 2012 sometime, February or March of 2012.

14       **Q.**   And after that point in time, after that briefing, you  
15                         have no knowledge about what Cardinal Health's Suspicious  
16                         Order Monitoring System, how it operated; correct?

17       **A.**   After that time, no.

18                          MS. WICHT: May I have a moment to confer, Your  
19                         Honor?

20                          THE COURT: Yes.

21                          (Pause)

22                          MS. WICHT: That's all I have. Thank you very  
23                         much.

24                          MR. NICHOLAS: Yes, Your Honor, I do have some  
25                         questions.

1                   THE COURT: Go ahead.

2                   CROSS EXAMINATION

3 BY MR. NICHOLAS:

4 **Q.** Good afternoon, Mr. Rannazzisi. How are you?

5 **A.** Fine.

6 **Q.** You and I, we met once before on Zoom?

7 **A.** Yes, we did.

8 **Q.** Do you remember that?

9 **A.** I do remember that.

10 **Q.** Good. It's not the most satisfactory way to meet  
11 people but, you know, --

12 **A.** It's nice meeting you in person.

13 **Q.** Same here.

14 **A.** Of course under these circumstances.

15 **Q.** Yeah, right. And I will say as we get set up  
16 technically that I have a tremendous misfortune of being --  
17 of having my examination begin at 4:25 in the afternoon on a  
18 long Wednesday, so I apologize for that.

19                  I want to apologize to the Court in advance in case I  
20 can't finish today. It's just one of those things. I'm not  
21 going to be that long, but I'm not sure I can get done by  
22 5:00. So please forgive me in advance.

23 **A.** Actually, this was the same circumstance we were under  
24 the last time.

25 **Q.** You know, you're absolutely right. You have a good

1 memory.

2       Okay. I guess I'll just begin by asking you this  
3 question. You have testified both yesterday and today that  
4 at least during your time at, you know, in your supervisory  
5 position between 2005 and 2015, the DEA did not approve  
6 Suspicious Order Monitoring Systems that were developed by  
7 distributors; is that correct?

8       **A.** That is correct.

9       **Q.** Okay. And is it your testimony that the DEA did not  
10 approve such systems before your tenure?

11      **A.** DEA -- the policy that was in place before my tenure  
12 was the same policy -- I'm testifying from 2005 to 2015.  
13 But I was told that that was the policy when I got to the  
14 Office of Diversion Control in -- actually, in 2004 when I  
15 originally got to the Office of Diversion Control, that was  
16 the policy.

17      **Q.** You say you were told. Was there a written policy that  
18 so stated or are you just telling us what your recollection  
19 is of what you were told?

20      **A.** I'm telling you my recollection. I had briefings on  
21 any number of topics and I was -- when we came into that,  
22 that distributor initiative briefing when I started asking  
23 questions about suspicious order monitoring, they said that  
24 the Suspicious Order Monitoring Systems were up to the  
25 companies. And we would not intervene, or we would not tell

1                   them how to file them and they directed me to 1301.74(b).  
2                   Actually, that was the first time I actually looked at  
3                   1301.74(b).

4                   **Q.**       Were you aware that the DEA had approved a Suspicious  
5                   Order Monitoring System developed by AmerisourceBergen  
6                   between 1996 and 1998?

7                   **A.**       No.

8                   **Q.**       Okay.

9                   MR. NICHOLAS:   Ritchie, can we cull up AM-WV-0258?  
10                  And let's hand it out.

11                  May I approach, Your Honor?

12                  THE COURT:   Yes.

13                  BY MR. NICHOLAS:

14                  **Q.**       Do you recognize this document?

15                  **A.**       Yes, I've seen this document before.

16                  **Q.**       Is it an approval from the DEA of AmerisourceBergen's  
17                  Suspicious Order Monitoring System as of 1998?

18                  **A.**       I believe there's a request letter that goes along with  
19                  this. So this letter says, "We're granting approval to your  
20                  request to implement on a nationwide basis your newly  
21                  developed system to identify and report suspicious orders  
22                  for controlled substances and regulated chemicals as  
23                  required by federal regulations."

24                  But I believe there's another letter that discusses  
25                  what the approval actually -- what the request for approval

1       is.

2       **Q.**     Well, there's a series of letters and we will go  
3           through them. But right now I'm asking you to look at this  
4           letter and tell me whether it is an approval of  
5           AmerisourceBergen's newly developed system to identify and  
6           report suspicious orders for controlled substances and  
7           regulated chemicals as required by federal regulation.

8       **A.**     That's what this letter says, yes. But --

9       **Q.**     Okay.

10      **A.**     -- I'd like to see the request letter that's attached  
11           to it.

12      **Q.**     We will get to that. We will get to the  
13           correspondence. But looking at this letter -- well, let's  
14           back up. The letter is written to Chris Zimmerman, the  
15           Director of Regulatory Compliance and Security Services for  
16           Bergen Brunswig Corporation. Do you see that?

17      **A.**     Yes.

18      **Q.**     Okay. And Bergen Brunswig is the predecessor of  
19           AmerisourceBergen; correct?

20      **A.**     Yes.

21      **Q.**     Okay. And the letter is written on U.S. Department of  
22           Justice letterhead; correct?

23      **A.**     That's correct.

24      **Q.**     And it says "Drug Enforcement Administration" under  
25           that; right?

1       **A.**    Yes.

2       **Q.**    And it's dated July 23rd, 1998; correct?

3       **A.**    Yes.

4       **Q.**    Okay. Now, it's signed by Patricia M. Good. Do you  
5 see that?

6       **A.**    Yes.

7       **Q.**    And she was the Chief Liaison and Policy Section,  
8 Office of Diversion Control. Do you see that?

9       **A.**    Yes.

10      **Q.**    Now, I also want to ask you about the cc's because this  
11 was cc'd to DPMs. Let's start with DPMs.

12      **A.**    Yes.

13      **Q.**    Does that stand for Diversion Program Managers?

14      **A.**    Yes.

15      **Q.**    Okay. How many Diversion Program Managers were there  
16 in 1998?

17      **A.**    I, I don't know how many there were in 1998.

18      **Q.**    Can you give me a ball -- can you ballpark it?

19      **A.**    Well, there's 21 field divisions. I'd guess there  
20 would be about half, so probably, maybe 10 or 11.

21      **Q.**    So this was cc'd to 10 or 11 Diversion Program,  
22 Diversion Program Managers; correct?

23      **A.**    That's correct.

24      **Q.**    All right. What does OD/D stand for? Is it Office of  
25 Diversion Control?

1       **A.** Yeah. I believe -- and, again, this is way before my  
2 time. But I believe that was designated for the Office of  
3 the Deputy Director.

4       **Q.** Okay. It was also cc'd to ODX. What's ODX?

5       **A.** That would be the executive assistant to the deputy  
6 assistant administrator.

7       **Q.** Okay. And if you see at the bottom it says "Subject:  
8 Approve Suspicious Order Monitoring System." Do you see  
9 that?

10      **A.** Yes, I see that.

11      **Q.** Is there anything about this letter that would lead  
12 anyone to a conclusion other than that as of July 23rd,  
13 1998, the DEA had approved Bergen Brunswig's newly developed  
14 system to identify and report suspicious orders for  
15 controlled substances and regulated chemicals as required by  
16 federal regulation?

17                  THE COURT: Mr. Ackerman.

18                  MR. ACKERMAN: Objection, speculation, foundation,  
19 calling for an opinion.

20                  THE COURT: Overruled. The question was: Is  
21 there anything about this letter that would -- I think he  
22 can answer that.

23                  THE WITNESS: When I look at a letter like this, I  
24 would like to review what the actual request was before  
25 because I know it says "Subject: Approve Suspicious Order

1 Monitoring System." But, quite frankly, I don't -- I've  
2 never seen this, this -- the bottom of the thing with the  
3 cc's, usually that's on a separate, a separate paper  
4 separated from the actual correspondence.

5 So I'm just -- I'm not saying this is wrong, but I'm  
6 just -- I -- before I comment on it, I'd like to see what  
7 you're actually request, requesting from DEA before you get,  
8 you know, my response because I don't know. I mean, I  
9 wasn't there in 1998 and I don't know exactly what you  
10 requested from DEA.

11 BY MR. NICHOLAS:

12 Q. All right. Well, just so, just so there's no  
13 uncertainty on the record, this document and this  
14 version of this document was produced by the DEA from  
15 their files.

16 A. Okay.

17 Q. So if you're, if you're suggesting there was something  
18 improper about it --

19 A. Absolutely -- I'm not suggesting anything. I just --  
20 generally, when this cc is written like this, it's on a  
21 separate page. That's all I'm saying. And that's why I  
22 just didn't -- I just -- I've never seen it set up like  
23 this. But, then again, this was 1998.

24 Q. It was 1998.

25 A. So -- but, again, I just can't give you an answer

1 without seeing what the actual request was.

2 **Q.** Well, on its face, it's an approval; correct?

3 **A.** On its face, it looks like an approval.

4 **Q.** And when it was cc'd --

5 THE COURT: Mr. Farrell.

6 MR. FARRELL: Objection. We're going to repeat  
7 the foundation objection. This witness has said he wasn't  
8 there. And to be fair to both sides, this document was  
9 discussed at length in the Prevoznik deposition through a  
10 30(b)(6) witness proffered by the DEA.

11 MR. NICHOLAS: I don't know what relevance that  
12 has to this.

13 THE COURT: Well, I think you need to move on. I  
14 think you're kind of beating this into the ground, Mr.  
15 Nicholas.

16 MR. NICHOLAS: Okay. I certainly don't want to  
17 beat anything into the ground.

18 BY MR. NICHOLAS:

19 **Q.** So why don't we go to the correspondence that  
20 preceded this approval between -- that occurred between  
21 1996 and 1998. And let's start with -- let's go to  
22 exhibit AM-WV-00781, please.

23 And what I'm handing out is another, is another copy of  
24 the approval letter. But attached to this exhibit is a  
25 series of correspondence that I will ask you about. And

1       this is the correspondence that you were asking me about,  
2 Mr. Rannazzisi.

3                   MR. NICHOLAS: May I approach, Your Honor?

4                   THE COURT: Yes.

5                   THE WITNESS: Thank you very much.

6                   MR. FARRELL: Without belaboring the point, again,  
7 objection to the foundation with this witness with this  
8 series of documents. The record is going to have much more  
9 detail from other witnesses with direct knowledge including  
10 the DEA.

11                  THE COURT: Well, I think this is  
12 cross-examination and I think Mr. Nicholas can use this as a  
13 basis to conduct his cross to a certain extent.

14                  So go ahead, Mr. Nicholas. I overrule the objection.

15                  MR. NICHOLAS: Thank you, Your Honor.

16 BY MR. NICHOLAS:

17                  **Q.** Let's start with, let's start with -- first of all,  
18 just for the record, this is -- this document is already  
19 admitted in evidence, as was the prior document.

20                  So moving on from there, if you will turn to Page 00009  
21 which is the September 30th, 1996, letter to Mr. Thomas  
22 Gitchel. We can start with that. Tell me when you're  
23 there.

24                  **A.** To Thomas Gitchel?

25                  **Q.** Yes.

1      **A.**     December 30th did you say?

2 Q. September 30th.

3           **A.**     Okay. I got it.

4 Q. And if you look at the first -- well, this letter is  
5 dated September 30th. It's to Mr. Thomas Gitchel who as of  
6 that date was the Chief Liaison and Policy Section, Drug  
7 Enforcement Administration, United States Department of  
8 Justice. So he was Patricia Good's predecessor; correct?

**A.** That is correct.

10 Q. Okay. And the letter was sent by Chris Zimmerman from  
11 AmerisourceBergen; correct?

12 | A. Yes.

13 Q. And Chris Zimmerman was the manager of corporate  
14 security -- I'm sorry -- for Bergen Brunswig at that time;  
15 correct?

16 | A. Yes.

17 Q. And Mr. Zimmerman begins his letter by saying, "The  
18 purpose of this letter is to introduce the Drug Enforcement  
19 Administration, DEA, to an innovative new system under  
20 development by Bergen Brunswig Drug Corporation, BBDC, to  
21 monitor and report suspicious orders of controlled  
22 substances which fit the suspicious order criteria outlined  
23 in 21, C.F.R., Section 1301.74(b)."

24 Do you see that?

25           **A.**       Yes.

1       **Q.**    So this was AmerisourceBergen -- this was Bergen  
2              Brunswig's initiative. This was not initiated by the DEA.  
3              Right?

4       **A.**    It appears that way, yes.

5       **Q.**    And the next sentence that begins the next paragraph  
6              says, "By way of background, as you know, BBDC participated  
7              in the development of a model excessive purchase report now  
8              in use by many distributor registrants."

9              Do you see that?

10       **A.**    Yes.

11       **Q.**    Okay. And if you go to the -- if you go to the last  
12             sentence of the paragraph, it says, "The report is produced  
13             in hard copy form monthly and is sent via certified mail to  
14             each DEA field office having responsibility for the  
15             reporting BBDC locations."

16              Do you see that?

17       **A.**    Yes.

18       **Q.**    Now, you had spoken in your direct examination about  
19             the fact -- and you kind of -- you were describing it as  
20             something you were unhappy with, about the fact that these  
21             reports only came monthly to you. Do you recall that  
22             testimony, that they didn't come in real-time?

23       **A.**    Well, they weren't suspicious order reports. They were  
24             excessive purchase reports.

25       **Q.**    Well, we'll get to that. That's, that's your view. I

1 understand that. But you also were saying that the  
2 excessive -- even if you call them excessive purchase  
3 reports, they weren't coming timely. They were coming only  
4 monthly. Do you recall that?

5 MR. ACKERMAN: Objection. I think that misstates  
6 his testimony.

7 THE WITNESS: I think what I said was --

8 THE COURT: Just a minute.

9 THE WITNESS: I'm sorry, Your Honor. I'm sorry.

10 THE COURT: I'm not sure -- overruled. Go ahead.

11 THE WITNESS: Yeah. I think what I said was these  
12 excessive purchase reports that came monthly are not  
13 suspicious order reports and they really have little value.  
14 That's what I said. I'm pretty sure I said that.

15 BY MR. NICHOLAS:

16 Q. If you go to the next paragraph, Mr. Zimmerman  
17 writes to Mr. Gitchel. "While feedback from different  
18 DEA users over the years has generally confirmed our  
19 belief that this report, standing alone, is a useful law  
20 enforcement tool, BBDC's suspicious order compliance  
21 program also involves the telephonic reporting of  
22 customer orders to DEA. In an average year, BBDC logs  
23 over 12,000 telephone calls to DEA field offices  
24 nationwide." And then it goes on.

25 Do you see that?

1       **A.** Yes.

2       **Q.** Okay. And if you turn to the next page, Mr.  
3 Rannazzisi, and go to the middle of the page, there's a  
4 paragraph that begins "against." And it says, "Against this  
5 backdrop, BBDC set to work on the development of a  
6 suspicious order reporting program that would provide better  
7 quality information to DEA in a more efficient manner."

8                  Do you see that?

9       **A.** Yes.

10      **Q.** So Bergen Brunswig was -- wanted to, wanted to develop  
11 a suspicious order reporting program that would provide  
12 better information to the DEA; correct?

13                  MR. FARRELL: Objection, foundation, speculation.

14                  THE COURT: Well, the letter itself speaks to that  
15 point, doesn't it, Mr. Nicholas?

16                  MR. NICHOLAS: It does. I'm really responding to  
17 the fact that Mr. Rannazzisi in his direct testimony has  
18 suggested time and time again that the distributors did not  
19 do anything to provide information that was useful to the  
20 DEA. This goes square dead on directly to that, or I feel I  
21 have to at least show the witness.

22                  MR. ACKERMAN: The concern we have, Your Honor, --

23                  THE COURT: Well, this is cross-examination. I  
24 think this is proper. And for the reasons Mr. Nicholas just  
25 said, I'll allow it.

1 BY MR. NICHOLAS:

2 Q. Now, Mr. Rannazzisi, I, I'm mindful of what the  
3 Judge just said which is that the letter largely speaks  
4 for itself, and it does. But -- so if you look at the  
5 next paragraph, I will, I will spare everyone in the  
6 courtroom my reading of the paragraph.

7 But if you look at it, you can see -- tell me if you  
8 agree that, that Bergen Brunswig is proposing, you know, to  
9 provide substantive information that it believes will be  
10 more useful to the DEA than it has been provided previously.

11 And it makes reference to an average of the customer's  
12 prior four months of orders, customers whose orders exceed  
13 by a specific percentage their prior four-month average  
14 order history would be printed on a summary report.

15 It says at the end of the paragraph -- here I am  
16 reading it -- the summary report would show the customer  
17 name, address, DEA number, item description, NDC number,  
18 order date, active ingredient volume ordered, active  
19 ingredient shipped, and customer allowance.

20 So AmerisourceBergen -- so Bergen Brunswig is proposing  
21 to create a program that would provide all of that  
22 information to the DEA. Correct?

23 A. That's what the letter says, yes.

24 Q. Okay. And the letter also, also talks about the manner  
25 of transmission and the timing of transmission on the last

1 page where it says, "Our intent is to receive DEA's  
2 permission to replace our current manner of daily suspicious  
3 order reporting, e.g. U.S. mail and telephone calls, with  
4 this daily electronic facsimile report."

5 And then it says, "We would like to have DEA input on  
6 the final product because DEA will be the primary users.  
7 Our suggestion would be to coordinate with one of your field  
8 offices, perhaps the Los Angeles office, to meet with our  
9 project development team."

10 Do you see that?

11 **A.** Yes.

12 **Q.** And it proposes beta testing to be done in connection  
13 with the Los Angeles office, the DEA's Los Angeles office;  
14 correct?

15 **A.** Yes.

16 **Q.** Okay. So that's, that's the opening -- that's the  
17 first thing that was written on this subject and it was from  
18 Mr. Zimmerman to Mr. Gitchel.

19 Now, let's turn to, let's turn to Mr. Gitchel's  
20 response which is dated October 29th, 1996. It's the next  
21 letter in the chain. And it's written to Mr. Chris  
22 Zimmerman and it's signed by Thomas Gitchel of the DEA. And  
23 it refers to Mr. Zimmerman's letter to him.

24 And, Ritchie, can you just highlight the first sentence  
25 of the second paragraph, please? Can you pull that out?

1           Now, it begins, "We have reviewed your proposal."

2       **A.**    Yeah.

3       **Q.**    The first sentence: "We have reviewed your proposal  
4           and feel it to be a viable alternative to the current  
5           system."

6           Do you see that?

7       **A.**    Yes.

8       **Q.**    All right. So let's go down to the next paragraph  
9           which says, "We note that," and just pull the whole  
10          paragraph out.

11          And you can see here by this paragraph that Mr. Gitchel  
12          is engaging in the substance of the proposal; correct?

13       **A.**    Well, the original request, the original request is to  
14          receive permission to replace current matter of daily  
15          suspicious reporting via U.S. mail or telephone calls with  
16          an electronic facsimile report. That's the request that was  
17          in this original email.

18       **Q.**    Well, I'm not going to argue with you about what the  
19          original letter says and doesn't say, other than to remind  
20          you, Mr. Rannazzisi, that there was an extensive description  
21          of the kind of substantive information that Bergen Brunswig  
22          proposed to provide to the DEA. You recall that; right?

23       **A.**    Well, it was laid out. But the only request that's in  
24          that email, or in that letter is a facsimile -- use of  
25          facsimile rather than telephone call or mail. And, and that

1       is the type of request that would, actually can be approved  
2       because it's just a change of reporting.

3       **Q.**    Well, --

4       **A.**    So --

5       **Q.**    So your testimony is that over this two-year period of  
6       back and forth --

7       **A.**    Uh-huh.

8       **Q.**    -- between Bergen Brunswig and the DEA, the beta  
9       testing, the substantive discussions, the testing at various  
10      sites, that all of that only had to do with whether  
11      information would be faxed as opposed to mailed. Is that  
12      your testimony?

13            MR. FARRELL: Objection, Your Honor. Again,  
14      foundation. He wasn't there. He doesn't have direct  
15      knowledge. And there's extensive testimony of people with  
16      knowledge other places in the record.

17            THE COURT: Well, he can ask him about it. And if  
18      he doesn't know anything about it, he can say he doesn't  
19      know anything about it.

20            Go ahead, Mr. Nicholas.

21       BY MR. NICHOLAS:

22       **Q.**    Do you know anything about it?

23       **A.**    I was not there during this time period. But I can  
24      only go with the letters you gave me. And these letters --  
25      this first one is a request for a change in the way that the

1 transmission of the suspicious order to the DEA offices.

2 And, yes, they would have to beta test that and it  
3 would go to multiple offices. And it takes time to beta  
4 test it. So I'm just saying that's what it says. I was not  
5 in headquarters at the time and I can't tell you exactly  
6 what they were doing.

7 MR. NICHOLAS: Ritchie, can we go back to the  
8 first exhibit that we looked at, AM-WV-02658.

9 BY MR. NICHOLAS:

10 **Q.** The first sentence says, "This is to grant approval  
11 of your request to implement on a nationwide basis your  
12 newly developed system to identify and report suspicious  
13 orders."

14 Do you see that?

15 **A.** Yes, I do.

16 **Q.** So it uses the word "identify." It separates it with  
17 an "and." And then it says "and report." Do you see that?

18 **A.** Yes.

19 **Q.** Okay.

20 **A.** You know, just if I may, you have two of the exact same  
21 letter and these letters are totally different, even though  
22 they're exactly the same.

23 One is -- it looks like -- it looks like they're the  
24 same dates. They're the same "to" and "from." They're the  
25 same content. But it looks like they're totally different.

1 One's got the chopped sheet on the bottom. One doesn't have  
2 a chop sheet. One has Patricia Good's name on the top -- on  
3 the bottom and the other one has it underneath the  
4 "sincerely." These are the same letters, the same exact  
5 letters but two different copies.

6 **Q.** What are you suggesting?

7 **A.** Well, I -- because this one doesn't have this  
8 underneath -- I'm not suggesting anything. They're the  
9 exact same letters.

10 **Q.** Yeah.

11 **A.** So you're asking me to testify about something I -- I  
12 wasn't in headquarters at the time, but I've been in  
13 headquarters long enough to see differences in the exact  
14 same memo. And I don't -- it looks like they're two  
15 different memos for the exact same thing on the same date.

16 **Q.** Are you suggesting anything improper?

17 **A.** I'm not suggesting anything --

18 THE COURT: He's saying he doesn't know anything  
19 about them.

20 MR. NICHOLAS: Okay. That's fine.

21 BY MR. NICHOLAS:

22 **Q.** Let me ask you this, Mr. Rannazzisi.

23 Did you ever come to understand when you took your --  
24 when you, when you became -- when you took over Diversion  
25 Control in 2005, were you made aware of the fact that this

1 approval was sitting out there that had been issued to  
2 Bergen Brunswig in 1998?

3 **A.** No, I was not.

4 **Q.** No one ever told you about it?

5 **A.** No. When I got to headquarters, they told me -- what I  
6 testified to was we don't approve Suspicious Order  
7 Monitoring Systems. That's what I was briefed on.

8 When we went into the distributor initiative -- the  
9 distributor initiative briefings, I understood that was part  
10 of the distributor initiative briefings, and we talked about  
11 that. It was in the letters. It was -- I mean, that's -- I  
12 can only go on my briefings.

13 I wasn't there in 1998. I don't know what they did in  
14 1998. But when I was there, I was briefed by very competent  
15 staff who knew exactly what they were doing. And I was  
16 briefed on Suspicious Order Monitoring Systems. That's how  
17 I could go in and, and evaluate what they were doing to make  
18 a determination how they were doing it and if they're doing  
19 it appropriately.

20 **Q.** Did you ever talk to Patricia Good about this approval  
21 letter?

22 **A.** No.

23 **Q.** Did you ever talk to Thomas Gitchel about this approval  
24 letter?

25 **A.** Thomas Gitchel was retired when I got there, and Pat

1 Good was about ready to retire when I got there.

2 **Q.** Did you ever talk to Mr. Zimmerman about the approval  
3 letter?

4 **A.** No, I did not. Again, I want to tell you I'm not, I'm  
5 not accusing you or anything. But I, I'm trained when I  
6 look at documents like this, especially DEA documents, we're  
7 trained to look at them to ensure. So I don't know why  
8 there's two different ones, but I'm not accusing you of  
9 anything. I wouldn't expect that you would do anything like  
10 that.

11 **Q.** No, I --

12 **A.** I'm just saying they're the same documents but they're  
13 two different -- it's the same document, just two different  
14 set-ups.

15 **Q.** All right. I understand. I appreciate that.

16 Let's go to P-000032, 032.

17 MR. NICHOLAS: And, Ritchie, if we could go to  
18 Page 3 of that document and highlight the last sentence of  
19 the -- the last sentence of the second paragraph which  
20 begins with the word "past communications."

21 BY MR. NICHOLAS:

22 **Q.** Now, this is your December 27th, 2007, letter to  
23 all the manufacturers and distributors; correct?

24 **A.** Yes, sir.

25 **Q.** And it wasn't directed to -- it wasn't a letter

1       specific to anyone. It was just a general letter to the  
2       industry. Right?

3       **A.** Yes, sir.

4       **Q.** Okay. And this sentence says, "Past communications  
5       with DEA, whether implicit or explicit, that could be  
6       construed as approval of a particular system for reporting  
7       suspicious orders, should no longer be taken to mean that  
8       DEA approves a specific system."

9                  Do you see that?

10       **A.** Yes.

11       **Q.** Okay. Prior to and other than this statement by you in  
12       this letter, are you aware of any writing that was ever  
13       directed to AmerisourceBergen that said, "Your prior  
14       approval is no longer valid"?

15       **A.** I, I don't recall any type of correspondence  
16       specifically to AmerisourceBergen, no. But -- and I've got  
17       to go back and look, but I believe that was part of the 2005  
18       distributor initiative. I don't have it handy, but --

19       **Q.** Well, right now I'm just asking you if anything --  
20       you're aware of any writing that was issued under your --  
21       while you were on your watch, for example, that was sent to  
22       AmerisourceBergen withdrawing approval of this, of this  
23       program?

24       **A.** I don't know of any, any type of correspondence that  
25       was sent specifically to AmerisourceBergen withdrawing that

1 program because I didn't know that program was approved, and  
2 I still don't. I'm not saying -- I just don't have any  
3 information because I was not back in headquarters in 1998.  
4 So I don't know if it was approved or not.

5 **Q.** So is it fair to say that as far as you personally  
6 know, this correspondence from you in December of 2007 would  
7 have been the first time that AmerisourceBergen was notified  
8 in writing that its prior approved program was no longer an  
9 approved program?

10 **A.** That letter --

11 MR. SINGER: Objection, Your Honor. This is  
12 contrary to the testimony here. Mr. Rannazzisi has  
13 testified that he didn't know that this was an approved  
14 program, and that it was policy not to approve programs. So  
15 I think the question mischaracterizes the testimony and it's  
16 misleading.

17 THE COURT: Well, the question was whether he knew  
18 of any prior notification that any program had not been  
19 approved. And that's a simple question. You can answer  
20 that.

21 THE WITNESS: And I don't know. I didn't know any  
22 program was approved. And, no, I don't know any program  
23 that -- you know, we didn't send any correspondence  
24 disapproving a program.

25 **Q.** Okay.

1                   MR. NICHOLAS: I think we could probably -- I, I  
2 have more to do. It's a good time for a break if it's all  
3 right with the Court.

4                   THE COURT: I assume you have more to go in the  
5 morning.

6                   MR. NICHOLAS: I do.

7                   THE COURT: And, Ms. Singer, you're going to have  
8 some redirect?

9                   MS. SINGER: I expect it to be very brief, Your  
10 Honor.

11                  THE COURT: Well --

12                  MR. NICHOLAS: Do you want me to keep going?

13                  THE COURT: How long do you think it will take?

14                  MR. NICHOLAS: 20 minutes, you know. I feel bad,  
15 you know.

16                  THE COURT: These things happen.

17                  And you're going to have some redirect, Ms. Singer?

18                  MR. SINGER: I expect to have some redirect. I  
19 will try to keep it brief, Your Honor, but probably about  
20 half an hour.

21                  THE COURT: Okay.

22                  Mr. Rannazzisi, it's probably cruel and unusual  
23 punishment, but I'm going to ask you to come back at 9:00 in  
24 the morning, sir, and we'll try to get you out of here  
25 sometime tomorrow morning.

1                   THE WITNESS: I'm more than happy to, Judge.

2 Thank you.

3                   THE COURT: All right.

4                   Ms. Singer, you're on your feet. Do you want to say  
5 something?

6                   MR. SINGER: I just figured it would be more  
7 efficient. It seems we're moving towards a recess.

8                   THE COURT: Well, I have no idea where this is  
9 going to go from here and I think, I think we'll recess  
10 until tomorrow morning at 9:00. I previously told you how  
11 unreliable I think lawyers can be and how much time they're  
12 going to take. I hesitate to go down this path. We'll see  
13 everybody in the morning.

14                   (Trial recessed at 4:58 p.m.)

15

16                   CERTIFICATION:

17                   I, Ayme A. Cochran, Official Court Reporter,  
18 and I, Lisa A. Cook, Official Court Reporter, certify that  
19 the foregoing is a correct transcript from the record of  
20 proceedings in the matter of The City of Huntington, et al.,  
21 Plaintiffs vs. AmerisourceBergen Drug Corporation, et al.,  
22 Defendants, Civil Action No. 3:17-cv-01362 and Civil Action  
23 No. 3:17-cv-01665, as reported on June 9, 2021.

24

25                   S\Ayme A. Cochran

s\Lisa A. Cook

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Reporter

Reporter

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June 9, 2021

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Date

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